IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY SKIN CARE, INC., and ZAHRA MANSOURI,)) Civil Action No. 06-601 (JFF)
Plaintiffs,)
v.)
LIMITED BRANDS, INC., and BATH &) Jury Trial Demanded)
BODY WORKS, INC.,) PUBLIC VERSION
Defendants.)))

APPENDIX OF EXHIBITS TO DEFENDANTS' **OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL**

<u>Description</u>	Ex	<u>hibit No.</u>
Defendants' Third Supp. Resp. to Plaintiffs'	First Set of Interrogatories E.	xhibit 1
BBW 5964-6077, 125250-125265	E	Exhibit 2
BBW 125125-125126	E	xhibit 3
BBW 1479-1496, 10863-11087	E	Exhibit 4
BBW 125034-125109	E	xhibit 5
BBW 125127-125248, 50833-50840, 99799	0-99802, 104839-104862 E	xhibit 6
BBW 82413	E	xhibit 7
BBW 73963-73966, 74661-74663, 74949-7	4952 E	xhibit 8
	Respectfully submitted,	
Dated: June 16, 2008	By:/s/ Francis G.X. Pileggi	

Dated: June 16, 2008

By:/s/ Francis G.X. Pileggi Francis G.X. Pileggi (Del. Bar No. 2624) Public Version Filed: June 25, 2008

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LABORATORY SKIN CARE, INC., and ZAHRA MANSOURI,)) Civil Action No. 06-601 (JFF)
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LIMITED BRANDS, INC., and BATH &) Jury Trial Demanded
BODY WORKS, INC.,)
Defendants.))

DEFENDANTS BATH & BODY WORKS, INC.'S AND LIMITED BRANDS, INC.'S THIRD SUPPLEMENTAL RESPONSE TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

Pursuant to Rule 33 of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."),

Defendants Bath & Body Works, Inc. ("BBW") and Limited Brands, Inc. ("LBI") (collectively
the "Limited Defendants") supplement herein their responses to Plaintiffs Zahra Mansouri's and
Laboratory Skin Care, Inc.'s (collectively "Plaintiffs") First Set of Interrogatories. The Limited

Defendants incorporate by reference the "General Objections and Comments" and specific
objections and responses set forth in Defendants Bath & Body Work, Inc.'s and Limited Brands,
Inc.'s previous Responses.

THIRD SUPPLEMENTAL RESPONSES

INTERROGATORY NO. 2

Provide a list of all BBW anti-bacterial products developed, manufactured, produced or sold by BBW or LBI since June 17,2003, and identify all persons responsible for the development, manufacture, production and sale of each product.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 2

The Limited Defendants incorporate herein the specific objections and responses identified in the Limited Defendants' previous Responses. Subject to the foregoing and the general objections referenced above, the Limited Defendants supplement their response to Interrogatory No. 2 as follows:

Regarding a list of anti-bacterial products:

The Limited Defendants have previously provided information and thousands of pages of documents regarding all of their anti-bacterial products. Plaintiffs have subsequently stated in writing that many of these products are not accused of infringement in this lawsuit. To the extent this request asks for information about those products, it is unduly burdensome and overly broad. The Limited Defendants reserve the right to supplement this response if necessary if additional products are accused of infringement.

Subject to the forgoing, the Limited Defendants state that they have developed, manufactured, produced or sold the following products: Anti-Bacterial Moisturizing Hand Lotion, Anti-Bacterial Foot Lotion (no longer being sold), and Anti-Bacterial Hand Cream (developed but never commercialized or sold). BBW hasalso sold the following "third party" products, which were developed, manufactured and produced by personal care companies not affiliated with LBI or BBW: the Redness Therapy Correcting Moisturizer by Murad, the Dermud Intensive Nourishing Cream by Ahava, and the Dermud Enriched Intensive Foot Cream by Ahava.

Regarding the identity of persons responsible for the development, manufacture and production of each product above:

REDACTED

Regarding the identity of persons responsible for the sale of each product above, the Limited Defendants have objected to this request as, *inter alia*, overly broad and unduly burdensome. It is not clear what Plaintiffs mean by "responsible." Conceivably this could include every sales associate in every BBW store. The Limited Defendants will provide the names of individuals who are most likely to have information about the sale of these products.

Regarding the identify of persons who are most likely to have knowledge of the development, manufacture, production and/or sale of the Anti-Bacterial Hand Lotion, the Anti-Bacterial Hand Cream and the Anti-Bacterial Foot Lotion, the Limited Defendants incorporate their Initial Disclosures by reference.

Pursuant to Rule 33(d), Fed. R. Civ. P., documents responsive to this Interrogatory No. 2, to the extent any such documents exist, which are not immune from discovery on the basis of the attorney-client or attorney work-product privileges have been produced to Plaintiffs. The Limited Defendants identify at least the following additional documents:

BBW 0125125.

INTERROGATORY NO. 3

On a product-by-product basis, provide a list of all ingredients contained in each BBW anti-bacterial product identified in response to Interrogatory No. 2 and identify the function and/or purpose of each individual ingredient.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 3

The Limited Defendants incorporate herein the specific objections and responses identified in the Limited Defendants' previous Responses. Subject to the foregoing and the general objections referenced above, the Limited Defendants supplement their response to Interrogatory No. 3 as follows:

Pursuant to Rule 33(d), Fed. R. Civ. P., documents responsive to this Interrogatory No. 3, to the extent any such documents exist, which are not immune from discovery on the basis of the attorney-client or attorney work-product privileges have been produced to Plaintiffs. The Limited Defendants identify at least the following additional documents:

BBW 0125125.

INTERROGATORY NO. 8

Identify all persons who have knowledge of or who have reviewed any written or oral opinions of legal counsel provided to or received by BBW or LBI concerning the '516 patent.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 8

The Limited Defendants incorporate herein the specific objections and responses identified in the Limited Defendants' previous Responses. Subject to the foregoing and the general objections referenced above, the Limited Defendants supplement their response to Interrogatory No. 8 as follows:

The Limited Defendants do not intend to assert an advice of counsel defense.

INTERROGATORY NO. 9

Identify all opinions of counsel provided to and/or prepared for BBW or LBI concerning the '516 patent, including the date of such opinion, whether it was written or oral, the provider and recipient, and state whether BBW or LBI intends to rely on any such opinions of counsel in defending against the allegation that BBW and LBI have willfully infringed the '516 patent.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 9

The Limited Defendants incorporate herein the specific objections and responses identified in the Limited Defendants' previous Responses. Subject to the foregoing and the general objections referenced above, the Limited Defendants supplement their response to Interrogatory No. 9 as follows:

The Limited Defendants do not intend to assert an advice of counsel defense.

INTERROGATORY NO. 10

For each claim of the '516 patent, identify all claim limitations, if any, you allege are not met by each of the BBW anti-bacterial products identified in response to Interrogatory No. 2. [SIC] and for each element that you contend is the basis for or supports your non-infringement position, explain in detail your construction of that claim element as used in the claims and provide a detailed explanation of why you contend the claim elements are not present in the BBW anti-bacterial product.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 10

The Limited Defendants incorporate herein the specific objections and responses identified in the Limited Defendants' previous Responses. Subject to the foregoing and the general objections referenced above, the Limited Defendants supplement their response to Interrogatory No. 10 as follows:

This request is overly broad to the extent that it requests non-infringement contentions for products that have not been accused of infringement, and for which Plaintiffs have not provided infringement contentions. Plaintiffs have only provided infringement contentions for BBW's Anti-Bacterial Moisturizing Hand Lotion. The Limited Defendants' response is limited to this

product. The Limited Defendants reserve the right to supplement their response if Plaintiffs accuse additional products of infringement.

Plaintiffs have asserted that the Anti-Bacterial Moisturizing Hand Lotion infringes Claims 1, 2, 3, 4, 5, 6, 7, 12, 13, 14, 15, 16, 17, and 18 of the patent-in-suit (the "asserted claims"). Of the asserted claims, only Claims 1 and 12 are independent. The Limited Defendants do not infringe any valid claim of the patent-in-suit for at least the following reasons:

When possible, claims should be construed to presume their validity. Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999). Applying this canon of construction here, the moisturizing composition of Claim 1 and the moisturizing method of Claim 12 both require the presence of an absorption enhancer in the moisturizer. See e.g., the '516 patent, col. 4, lns. 19-21, 66-67. Any other reading of those claims in light of the specification and prosecution history of the patent-in-suit, as well as the specifications and prosecution histories of related patents and applications, would render the asserted claims invalid as anticipated under 35 U.S.C. § 102, obvious under 35 U.S.C. § 103, and/or indefinite under 35 U.S.C. § 112.

REDACTED

The Limited Defendants reserve the right to supplement their response to this Interrogatory No. 10 if and when Plaintiffs assert that additional products infringe one or more claims of the patent-in-suit.

INTERROGATORY NO. 11

Explain in detail the complete factual basis for your contention that the '516 patent is invalid, including a detailed explanation of each legal theory upon which you base any invalidity contentions, identifying with particularity each event, disclosure, reference, or publication forming the basis for such contention, including each party or person with knowledge of any such event, disclosure, reference, publication and all documents and things that support, contradict or relate to your contention.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 11

The Limited Defendants incorporate herein the specific objections and responses identified in the Limited Defendants' previous Responses. Subject to the foregoing and the general objections referenced above, the Limited Defendants supplement their response to Interrogatory No. 11 as follows:

The patent-in-suit is anticipated by at least the following additional reference: U.S. Patent No. 5,416,075.

Pursuant to Rule 33(d), Fed. R. Civ. P., documents responsive to this Interrogatory No. 11, to the extent any such documents exist, which are not immune from discovery on the basis of the attorney-client or attorney work-product privileges have been produced to Plaintiffs. The Limited Defendants identify at least the following additional documents: BBW 011162-011278, BBW 0123595-0124952, and BBW 0124953-0125020.

INTERROGATORY NO. 12

Identify each piece of prior art to the '516 patent of which you are aware or on which you intend to rely to support your assertion that the '516 patent is invalid.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 12

The Limited Defendants object to this Interrogatory as premature, but recognize their obligation to supplement this response in accordance with the Federal Rules. Subject to the

Subject to the forgoing specific objections and the general objections stated above, the Limited Defendants respond to Interrogatory No. 12 as follows:

The Limited Defendants incorporate by reference their responses to Interrogatory No. 11.

INTERROGATORY NO. 19

On a year-by-year basis, since June 17,2003, state how much revenue has been received and how much profit has been earned by BBW and/or LBI for each of the BBW anti-bacterial products developed, manufactured, produced, sold or used by BBW and/or LBI, including but not limited to the Warm Vanilla Sugar and Coconut Lime Verbena products.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 19

The Limited Defendants object to this Interrogatory as premature, but recognize their obligation to supplement this response in accordance with the Federal Rules. Subject to the Subject to the forgoing specific objections and the general objections stated above, the Limited Defendants respond to Interrogatory No. 19 as follows:

Pursuant to Rule 33(d), Fed. R. Civ. P., documents responsive to this Interrogatory No. 19, to the extent any such documents exist, which are not immune from discovery on the basis of the attorney-client or attorney work-product privileges have been produced to Plaintiffs. The Limited Defendants identify at least the following documents: BBW 005964-006077 and BBW 0125250 - 0125265.

INTERROGATORY NO. 20

If you contend that any claim or claim term of the '516 patent requires claim construction, describe your proposed construction of each claim or claim term and the bases for such construction, and identify the support for your construction of the claims and claim terms, including an identification of all portions of the specifications and/or prosecution histories and

any extrinsic or other evidence relied upon by you to support the construction.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 20

The Limited Defendants object to this Interrogatory as premature, but recognize their

obligation to supplement this response in accordance with the Federal Rules. Subject to the

Subject to the forgoing specific objections and the general objections stated above, the Limited

Defendants respond to Interrogatory No. 20 as follows:

The Limited Defendants note their obligations under Paragraph 8 of the Amended

Scheduling Order, dated April 25, 2008 (D.I. 57), which requires the parties to exchange

contentions regarding claim construction by September 12, 2008.

Respectfully submitted,

Dated: June 11, 2008

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served on this 11th day of June, 2008 via email and U.S. First Class Mail, upon the counsel of record shown below:

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EXHIBIT 2

REDACTED

EXHIBIT 3

REDACTED

REDACTED

United States Patent [19] Ferguson et al.

[11] Patent Number: [45] Date of Patent:

6,045,813 Apr. 4, 2000

[54] LOTIONS AND GELS WITH ACTIVE INGREDIENTS IN BEADS

[75] Inventors: John Ferguson, Westerville; George Zlets, New Albany, both of Ohio

[73] Assignce: Bath & Body Works, Inc., Reynoldsburg, Ohio

[21] Appl. No.: 09/050,536

[22] Filed: Mar. 30, 1998

[51] Int. CL7 A61K 7/00, A51K 7/021;
A61K 9/48; A61K 9/50
[52] U.S. Cl. 424/401; 424/63; 424/451;
424/455; 424/452; 424/489; 514/844; 514/862;
514/847; 514/951; 514/952
[58] Field of Search 424/451, 455,
424/456, 401, 489, 63, 452; 428/402.2

References Cited

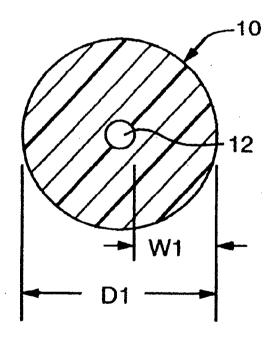
U.S. PATENT DOCUMENTS

Primary Examiner—James M. Spear Attorney, Agent, or Firm—Colucci & Umaos

ABSTRACT

A flowable personal care or cleaning composition, comprising a carrier and finible beack disturted in the carrier, the beack containing an active ingredient and enclosing the active ingredient in a wall of bead material, the active ingredient amounting to approximately 0.5-5.0% by weight of the bead including its wall material and the active ingredient and

20 Claims, 3 Drawing Sheets



U.S. Patent

Apr. 4, 2000

Sheet 1 of 3

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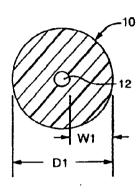


FIG. 1

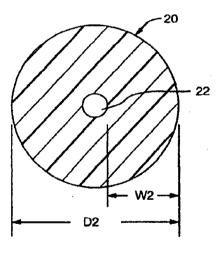


FIG. 2

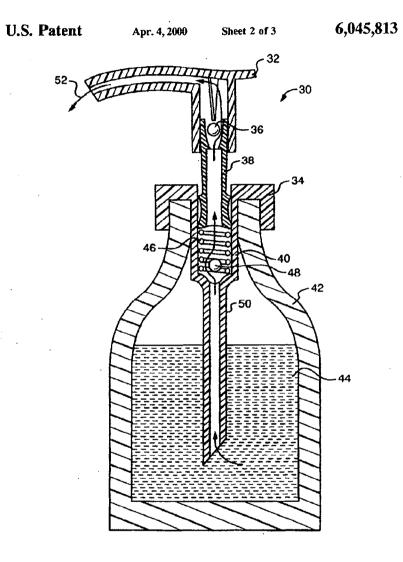


FIG. 3

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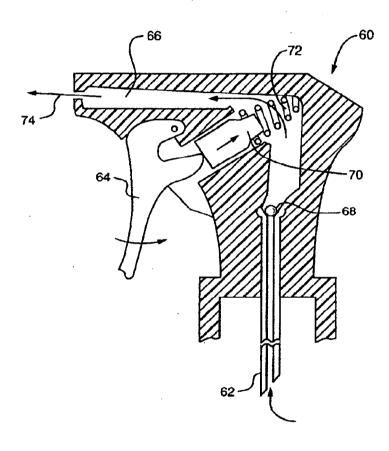


FIG. 4

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LOTIONS AND GELS WITH ACTIVE INGREDIENTS IN BEADS

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates, in general, to skin care and household products, and in particular, to a new and useful gel or lotion which can be used for such things as sanitizing the hands, moisturizing and adding fragrance to the skin, a shampoo, a liquid soap product, a household cleanser and the like, which includes active ingredients such as antibacterial agents or essential oils, which are captured within friable beads.

The use of microencapsulation is known in various fields. Microencapsulation involves the capturing of active ingradients within a shell which can be broken or dissolved, depending on the environment in which the active ingredient is to be released. Generally, however, microencapsulation has been utilized in the pharmaceutical and quasipharmaceutical field, to time release medication, vitamins or minerals by encapsulating the active ingredient within a shell which dissolves over time in the stomach.

The use of encapsulated materials to control release and improve the stability of composition is well established. Encapsulation efficiency can be improved by reducing the relative percentage of the protective wall material and increasing the quantity of the core encapsulate. Emphasis has been place on maximizing the absolute delivery of the encapsulated core material. The present invention teaches the use of macro capsulate (500–1,500 microns) as a way to visually mark the coverage of personal care, bousehold and pharmaceutical preparations. Further, this invention teaches a very low concentration of core material (0.5% to 5.0%) is an effective way to provide controlled release and visual indication of product coverage, which is contrary to general teaching in this field. The present invention can also be used to mix incompatible, quasi-compatible or complimentary ingredient (carrier formula and beads contents) at the time of

SUMMARY OF THE INVENTION

An object of the present invention is to take advantage of rupturable beads in a liquid gel or lotion, which contain small amounts of active ingredients for use in cleansing, treating or adding fragrance to the skin of a user or for other household uses.

According to the present invention, the beads may contain either an antiseptic such as Triclosan, or essential fragrance oils, referred to as essential oils, for imparting fragrance so and/or other active ingredients to the skin such as moisturizers and the like, or as cleansers for other surfaces.

It was found by the inventors that the use of beads which were too flexible would allow the beads to survive the manufacturing process, but the beads would not then readily 55 break when the lotion or gel was rabbed onto the skin. One hurdle which was overcome by the present invention was to utilize beads of proper diameter and wall thickness which did not rupture during the manufacturing process, but, after a 24 to 48 hour induction period were friable (pulverizable on rupturable) when the lotion or gel was rubbed onto the skin or dispensed through a restrictive orfice. It was found that beads that contained only about 0.5 to about 5% by weight active ingredient and which are mostly wall material, could be used according to the present invention and in fact, 65 added an additional advantage in that the wall material could contain coloring which would act as a indicator to the user

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both that enough of the active ingredient was present on the hands or surface and secondly, that the active ingredient has been released in that the color would smear, indicating rupturing of the beads.

The use of beads also permitted the inventor to utilize a chull fragrance system. One fragrance is in the carrier lotion which carries the beads. This fragrance is tailored to be pleasant when exposed to the air. Another different fragrance, however, was used with the active ingredient in the beads, in particular, in the version of the invention for dispensing essential oils to the skin. This different fragrance was selected both to give a different scent, but also to be of the type of fragrance which is best activating when coming into contact with the skin. It is known in the field of fragrances that some fragrances are more effective as "room freehoners" and others are more effective as "perfunes" in that they are more active and have different advantageous effects when applied to the skin. By providing the active ingredient with the skin compatible fragrance in the beads, two separate fragrances could be utilized in the product, and fragrances which were tailored for their particular use, that is, either to give out a fragrance imply upon contact with the air or to give out a fragrance best when in contact with the skin.

The lotion and gels of the present invention whether for containing the essential oils or the antibacterial agent, have preferred approximate diameters of about 500 to 900 microns with a wall thickness of about 210 to 440 microns.

Compositions in the form of a shower gel containing beads with essential oils, are generally about 1000 to 1500 o microps in diameter with a wall thickness of about 460 to about 740 microps.

Despite the relatively small volume within the bead wall, which is available for containing the unibacterial agent or essential oil at rate of only about 0.5 to about 5% by weight of the overall bead, sufficient active ingredient is present to satisfy the purpose of the invention and also to add the indicating function and provide sufficiently robust beads. Accordingly, the seeming disadvantage of baving beads with very large wall thicknesses, is more than compensated by the other advantages of indication and friability characteristics.

The various features of novelty which characterize the invention are pointed out with particularity in the claims amerated to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying drawings and descriptive matter in which a preferred embodiment of the invention is illustrated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a bead for containing an active ingredient and for use in a lotion composition of the present invention;

FIG. 2 is a view similar to FIG. 1 of another embodiment of the bead for use with a gel of the present invention;

FIG. 3 is a schematic sectional view of a dispenser for lotions and gels which can be used to dispense the composition of the present invention and to practice the method of the present invention; and

FIG. 4 is a schematic sectional view of a sprayer mechanism which can also be used to dispense the composition of the present invention and in accordance with the method of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, FIG. 1 illustrates a bead generally designated 10 in accordance with the present

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invention having a diameter D1 of about 500 to 900 microns and a wall thickness Wt of about 210 to 445 microns. Although these measurements are approximations, they are representative and illustrate the fact that bead 10 is mostly representative and illustrate the fact that bear 10 is mostly wall thickness with only a very small, roughly spherical volume 12 remaining to contain the active ingredients whether it is the antibacterial agent or the essential oils of the present invention. By weight, beard 10 is about 98 to 99.5% wall material and only about 0.5 to about 2% active ingredient in volume 12. dient in volume 12.

These timensions are representative for the beads used in the lotions of the present invention, both the essential oil containing lotion referred to as an "Aromatherapy" lotion, and an antheacterial lotion containing Triclesan or other aminocterial agent.

and animoacistal stem. Containing Iriclosan of other anibacterial agent.

FIG. 2 illustrates a bead generally designated 20 useful in gels of the present invention such as shower gels and shampoo gels. In this embodiment, the diameter D2 is about 1000 to 1500 microns and the wall thickness W2 is about 420 to 740 microns. This also kaves a volume 22 for containing only about 0.5 to about 5.0% by weight active ingredient, the bead being mostly inert wall material.

Although intuitively, this would appear to be a disadvantage in that very small amounts of active ingredients are present, in fact, the thick wills of the beads compensate any disadvantages by providing the advantages of dual fragrance capabilities and beads which are not friable during the manufacturing process involving mixing together and loading of the lotious or gels into bottles. The beads, after a 24 to 48 hour introduction period, do become friable when they are massaged into the skin or scalp, however, causing the beads to break and thus releasing their active ingredients in sufficient quantities to have the desired effects. In addition, the wall material can contain a harmless non-toxic colorant the walt material can contain a harmless non-toxic colorant the wall material can contain a harmless non-loxic colorian which is water soluble or water disbursable and which adds to the effect of the invention by providing a visual que to the amount of active ingredient being worked into the skin and also the fact that sufficient mechanical massaging has taken place to activate the ingredients by upturing the beads and smearing to color. The beads, in effect, rupture and smear the provided of the prov something to color. The coests, in effect, replace and shows across the skin, releasing the active ingredient. The bead material is easily washed away with water, however, so that no adverse effect occurs. For example, a white, yellow or pink translucent or clear lotion or gel may contain blue or

Another use of the invention involved a hydro alcoholic solution capable of dispensing a fragrance or providing an effective disinfective alcohol concentration to the skin or a emercine disintective atconor concentration to the sign of a hard surface. In this application, the encapsultated bead breaks inside the pump mechanism, intimately mixing and coloring the solution. Thus a clear solution with colored breaks dispensed throughout can be dispensed onto the skin as a colored product. This can be used for both aesthetic purposes and functionally to mark product placement on the skin or some other surface.

An example of the shower gel has the following approximate composition and range of amounts:

TABLE I

Ingrediess	Representative Amount	Range
Water	45	35-70
Thickener	1.2	0.5-5
Surfactant	36	12-40
Fragrance	2	0.5-3
Emollient	2	0.5-5

An example of a lotion according to the present invention

Ingredient Representative Amount Range 80 40-90 water Enrolsider Enrollient Botaniesk 3-10 2-10 0.7 1.0 0.3 Fragmoc

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TARIF 2

In the lotion, the beads amount to approximately 0.5 to 2.0% by weight of the overall composition and in the get, the beads amount to 0.5 to 1.0% of weight of the overall composition.

To be effective, the wall material must be colored and possess sufficient strength to withstand normal manufacturing mixing, pumping and filling operations. In use, the wall material must be friable enough to break easily with hand pressure or implement (cloth, sponge or paper) wiping.

Ideally, the macro capsule should have an impervious wall material in the dry state and gradually soften in the cleaning, cosmetic or pharmaceutical preparation. This characteristic allows the capsules to be processed fresh, in a hardened state, and become friable when equilibrium is established with the preparation.

Capsule breakage can be accomplished by hand or imple-Capsate treakage can be accomplished by and of ingre-ment pressure after the preparation bas been dispensed. It can also be fractured at the time of application by dispensing the preparation through a mechanical pump or restricted orifice. This latter technique allows the colored wall material and its encapsulate come to intimately mix with the prepa-ration at the precise moment of use. The resultant product is colored and provides strong visual indication of its cover-

If the internal clearances of the pump are smaller than the D1 or the D2 in FIGS. I and 2 herein, the cross sectional diameter of the bead, it will rapture inside the pump and intimately mix with the rest of the formula. This could lead to the mixing of two quasi-compatible or incompatible ingredients (formula and bead) to produce neutralization, beat, color or some other chemical reaction.

After the beads are placed in solution (aqueo hydroalcoholic) the wall slowly softers and becomes friable. This induction period is dependent upon time, temperature and the sarface activity of the formula. For the examples, this induction period is 24 to 48 hours at room temperature.

The following examples demonstrate the utility of the invention across three broad product categories: pharmacentical, personal care and cleaners. These examples also demonstrate the importance of the induction period to produce frability. Finally, the examples demonstrate the bead release mechanics, via hand or implement wiping and internal breakage, via mechanical dispensing.

In all of the applications cited, the 500 to 1500 microns (31 thousandths to 58 thousandths of an inch) cellulose. (31 thousandles to 26 thousandles of an inch) cellulose, hotose, bydroxypropyl methyl cellulose spherical macro beads identified by the trademark UNISPHERES manufactured by Induchen AG of Dubendorf, Switzerland and with the generalized formula listed below were added to the formula last. The formulas were then transferred by pouring. for laboratory preparations), or by pumping, (for commer-es cial preparation), to their final containers. Standard dia-phragm or displacement pamping equipment con be used so long as the beads have not passed through their induction

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period; i.e. when first added to the formula they are not shear sensitive as defined by the examples described below.

TABLE 3

Generalized Bead Compo-	<u>piling</u>
Material	% by weigh
Lectose Cellulose Hydroxypropyl Methyl Collulose Color	98
Perfame or tricloma	
	100

Product or Example B was then allowed to remain at room temperature for 48 hours. After this induction period, product dispensed from the tube quickly broke under hand pressure. The pressure of the blue colored beads clearly marked where the lotion had been dispensed. When the lotion was spread onto the skin, the hand pressure caused the blue colored beads to quickly break citing a trail of color which designated to the user product coverage. As the lotion was rubbed into the skin, the blue dissipated and left no recognizable color on the skin.

In a similar fashion, after 48 hours at room temperature, the product in Product B was dispensed through each of the

the product in Product Piwas dispensed through each of the two Calmar dispensers previously described. The results are described below. The pump of FIG. 3 is a high volume pump (O8 to 1.2 g per actuation) and has internal tolerances greater than be cross-sectional diameter of the bead. That is

TABLE 4

Anti-Bacterial Water je Oil Lotion Porumbas										
Mesoial	A	В	c	D	E	F	G	н	ſ	Function
Water	qs	QS	QS	Qs	QS	QS	QS	QS	QS	Currier
Triclaum	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	Biocids
Glycenia	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	Humectant
Steenic Acid	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	Empleifics
Tricthonol	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	3.0	Neutralizer
Amiet Cetyl Alcohol	_	-	0.75	0.75	0.75	0,75	9.75	0.75	0.75	Emulsifies
Glycol Steamte	-	-	3.5	3.5	3.5	3.5	3.5	3.5	3.5	Emollicas
Dimethicone	_	-	D.25	0.25	0.25	0.25	0.25	0.25	0.25	Occlusive Agent
Wheat Germ Oil	-	-	-	0.4	0.4	0.4	Œ.	0.4	0.4	Conditioning Agent
Pentheool	-	_			0.1	0.2	0.1	0.1	0.1	Conditioning Agent
Perfume, Apple	-	_		_	 .		1.0	1.0	1.0	Fragrance
F, D, & C Yellow 6	_	_	_	_		_	-	_	100.0	Colorant
Ultromaries		1.0		3.0	_	0.5		0.75	3.0	Biocide,
Bine Beads										Vicus! Indicator
	100	100	100	100	100	100	100	100	100	

Examples A through H (Pharmaceutical Application): Various triclosan containing anti-bacterial oil in water emulsion were prepared by dispensing an aqueous phase into the oil phase and mixing until uniform. Color, fragrance, and skin conditioning agents were added to modify the preparation for various applications.

The product in example A is an opaque white emulsion. 50 When applied to the skin it is difficult to visually gauge product coverage. Product from example B, containing the lactose-cellulose beads was placed in a tube and in two 8 oz. PVC plastic bottles fitted with commercially available dispensers, one of which is FIG. 3. This and other suitable 55 dispensers are available from Calmar Inc. of City of dispensers are available from Calmar Inc. of City of Industry, Calif.

Industry, Calif.

Within an bour of preparation and filling, it was attempted to dispense Example B from another lotion pump dispenser with small complex internal passages. The beads quickly so clogged the dispenser and product could not be dispensed. Product B was also dispensed form the bottle using the high volume of FIG. 3 pump. This time the product dispensed easily and the individual blue beads were readily observed in the white below. in the white lotion. However, like the Product B dispensed 65 from a tube, the beads were hard and could not be broken by hand rubbing.

the blue beads passed through the pump mechanism without breaking and was dispensed onto the skin as a white lotion with discrete blue beads dispensed throughout, As with the product dispensed form the tube, the white lotion with blue beads quickly broke with hand pressure, marked where the lotion had been, and quickly faded away leaving no recognizable color.

The other Calmar pump (a model MD-150) is a low volume pump (0.10 to 0.25 g per actuation) with internal tolerances smaller than the cross-sectional diameter of the tolerances smaller than the cross-sectional diameter of the beads. When dispensed, the internal prump mechanism in the MD-150 broke the beads, mixed them with the dispersed phase and the product exited the pump as a light blue bomogeneous lotion. That is, the blue beads broke inside the pump at the discharge valve inside the spin chamber and mixed into the white lotion to produce a single-phase light blue lotion. The light blue lotion was easily discernable on the skin and quickly dissipated as it was rubbed into the skin. In a similar fashion, the product example pairs described by CTD, E/F and G/H behaved in the same fashion. The white lotions in C, E and G were functional but did not provide the lotions in C. E and G were functional but did not provide the sources in C. E and of were interned not use to provide user with a clear indication of product location or coverage. The white lotton with blue beads; D. F and H, after a 48 hour induction period, could be dispensed as an intack discrete two component system through a tube or a mechanical

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pump; e.g. the Calmar pump of FIG. 3 whose internal pumping tolerances or final restriction metering orifices were greater than the cross-sectional diameter of the beads. If the pump tolerances of final metering orifices were less than the cross-sectional lead diameter, the blue Triclosan 5 beads broke and thoroughly mixed together to produce a homogenous single light blue lotios. The color of lotion could be easily adjusted by varying the concentration of blue Triclosan beads in the final formula. The higher the bead concentration, the more intense the homogeneous blue color.

This discovery also permits the preparation of two chemically incompatible ingredients to exist together in either the continuous lotion phase or dispersed head phase. To demonstrate this, a small amount of F, D & C Yellow No. 6 was added to preparation H to produce Example 1, a light yellow lotion with blue beads. When dispensed from a tube or a bottle fitted with a FIG. 3 pump, after the 48-hour induction period, the user could readily observe on the skin a light yellow lotion with blue Trictosan beads. This turned into a light green lotion as the hand pressure broke the beads and the blue and yellow mixed together. If a Calmar MD-150 pump is used, the light yellow lotion with blue Triclosan beads in the bottle will dispense as a homogenous light green lotion because the internal pump mechanism will heak the blue beads and thoroughly mix them with the yellow lotion.

To further demonstrate the utility of this invention, the following examples are listed in Table 5 below. In all cases the beads were added to formula G for 24 to 48 hours before the experiment was conducted.

TABLE 5

	Encapsulated Bead Color Dispensing Options						
Par	periment	Appearance Before Dispersing	Calmar Dispenser	Appearance After Dispensing			
1.	Formula G + 1% blue benda	White Lotion with Blue Beads	MD-150	Uniform Light Blue Lotion			
2	Formula G + 6% blue boads	White Lotion with Blue Boads	MD-150	Uniform Dark Blue Lotion			
3.	Formula G + 1% blue beads and 1% yellow beads	White lotion with Blur and yellow beads	MD-150	Uniform medium Green Lotion			
4.	Formula G + 1% blue beads	White lotion with purple beads	MD-150	Uniform medium Purple Lotion			
5.	Pormula I	Yellow Lotion with Blue Speckles	MD-150	Uniform medium Green Lotion			
6.	Formula I	Yellow Lotics with Blue Speckles	FIG. 3	Yellow lotion with Blue Speckles which Forrord a Medium Green Lotion When Robbed into the			

These experiments indicate a wide variety of colors and intensities can be created by either dispersing the appropriate concentration of colored beads in a white lotion or adding the appropriate concentration of colored beads to a colored lotion. The color can be created by fracturing the friable beads in the internal mechanical dispensing device when the pump tolerances are smaller than the cross sectional bead diameter. Alternately, the color can be created in since the color can be created in surface by dispensing the preparation through a tube or mechanical dispenser with internal metering tolerances greater than the cross sectional

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Those skilled in the art would readily recognize this discovery is also applicable to encapsulating one or more chemically reactive species within a bead and uniformly mixing the ingredient into the preparation at either the moment of mechanical dispensing or upon hand and/or implement pressure as the preparation is rubbed into the

In each of the foregoing formulas and experiments, the presence of the colored ultramarine blue beads containing the triclosan active provided the user with a visible marker that the antibacterial preparation was being correctly and uniformly applied to the treated area. This is especially helpful to users where under application could create secondary infection or over application could create undue surrounding tissue trauma.

This invention is also applicable to other uses such as disinfecting hand surface cleansers and personal care products where visible indication of product coverage or specialized encapsulation of ingredients are important for performance and functionality.

TABLE 6

Dini 5	afecting H	face Cl by Weig		mules	
Material		K	L	м	Pubetion
Ethyl Alcohol	65	65	65	65	Anti Microbal
Water	QS	QS	QS	QS	Solvent
Discopropyl Amize	0.5	0.5	0.5	0.5	Neutralizer
Carbopol 941	0.35	0.35	0.35	0.35	Thickening/ Suspending Agent
Aloe Vers Gel	_		0.5	0.5	Moimmizer
Perfume, Apple	_	_	1.0	0.1	Fragrance
Ultransmine Blue	=	0.5		1.0	Biocide, Visual
5 Triciosaa Beads					Indicator
	100	100	100	100	

Formulas J through M are transparent, thickened, alcohol gels with viscosities of 5,000 to 8,000 cps. Formulas J and K are suitable hard surface disinfectant formulas suitable for kitchen and other food contact sanitization applications. They are also disinfectant products for bathroom and other hard surface articles such as doorknobs, shopping cart handles and telephone receivers. The formulas were made by dispensing the Carbopol 941 into water, neutralizing it with disopropylamine and adding the alcohol. Perfume moisturizer and/or Triclosan beads were subsequently added.

The triclosan containing blue beads were added to formulas K and M and used within 30 minutes of preparation and after a 24 hour induction period. Formula K was dispensed with a trigger spray pump fabricated with a transparent plastic housing as shown in FIG. 4. This device is was chosen because the blue beads could be visually observed during the dispensing operation.

Formula J, when sprayed onto a white enameled surface, was difficult to visually observe for coverage. Ultramarine blue inclosase beads were added to produce Formula K. When sprayed through the trigger spray pump within thirty minutes of preparation the pump quickly clogged. Visual inspection of transparent pump mechanism revealed the beaks had become lodged in both the dip tobe leading to the piston chamber and in the piston chamber itself. Both areas were full of unbroken beads, rendering the pump nonfunctional. After 24 bours, Formula K was transferred to a new trigger spray pump of FIG. 4 was attached

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to the bottle. The formula easily dispensed through the pump. Visual inspection of the pump indicated the piston chamber contained a clear light blue homogenous solution indicating the clear continuous phase of the alcohol sanitizer had thoroughly mixed with the ultramarine triclosan bearts. When sprayed onto a white enameled surface, a light blue solution was readily observed. This light blue solution was easily wiped away with a paper towel yielding a clean, disinfected surface.

Formula L an instant hand sanitizer, was poured onto the hands and rubbed into the skin. Product coverage was difficult to observe. Formula M was poured onto the hands within 30 minutes of preparation. A clear alcohol gel containing bright blue speckles was readily observed. The formula when rubbed into the hands, was very uncomfortable. The beads were hard and granular and could not broken with hand pressure. After 24 hours, Formula M was poured into the hands. The transparent alcohol gel containing blue speeckles easily fractured with hand pressure marking where the product had been applied. The formula easily rubbed into the hands. The office was applied for the formula easily rubbed into the hands all left no observable colors.

Formulas N through O are transparent, thickened, surfactant cleaning solution with viscosaites of 8,000 to 20,000 gcps. As in the previous examples, the lactose/cellulose beads described in Table 3 required a 24 to 48 hour induction period before the beads became friable and easily broken by mechanical, hand or implement pressure. The colored lactose/cellulose beads used in Formulas O and O contained at 100% active perfume oil specifically designed to be substantive to the skin. This eocapsulated oil was different from the bulk fragrance in the shower gel. Bulk fragrances must be specifically formulated to be compatible with the preparation. They are incorporated into the final product swith solvents or emulsifiers to yield homogenous solutions or dispersions. Since most of the perfume will be either rinsed, wiped or washed away, it is a very inefficient process to directly apply perfume to an absorbent substrate such as skin and retain lasting fragrance benefit from the absorbed apperfume. Furthermore, the only fragrance effect that can be created is that fragrance which comes from the bulk perfume in the formula.

The examples listed in Table 7 demonstrate the ability to formulate a dual fragrance personal care product. This invention permits the user to experience both the fragrance from the bulk product during the shower or bathing activity and the same or different fragrance directly apply to the skin from a friable encapsulated fragrance bead. This produces a longer lasting fragrance benefit.

TABLE 7

Bash and Shower Formulas Percent by Wright								
Material	N	0	P	٥	Proction			
TEA Laurel Sulfate	18.0	18.0	18.0	18.0	Sprinctual			
Water	QS	QS.	QS	os	Solvent			
Carbopol 2020	1.2	1.2	1.2	1.2	Thickener			
Carbontesthylceflulous	0.1	0.1	G 3	0.1	Suspending Agent			
Tricthood Amino	1.3	1.3	1.3	1.3	Neutralizza			
Propylene Glycol	5.0	5.0	5.0	5.0	Rheelegy Costrol			
Ethyl Alcohol	4.0	4.0	4.0	4.0	Riscology Control			
Carbowas 400	0.9	6.9	0.9	0.9	Emulatifér .			
Citric Acid	0.1	0.1	0.1	0.1	pH Contro!			
Silicone Finid	2.0	2.0	20	2.0	Moistorizer			
Germebon II	1.0	ıo	2.0	1.0	Propervative			

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		TABL	E 7-0	ນຄຸຢາດດ	eđ				
5	Bath and Shower Formulas Percent by Weight								
	Moterial	N	0	P	0	Punction			
•	Pragrance:								
	HARA3025OR	2.0	2.0	2.0	2.0	Perfame			
10	D&C Violet #2	0.007	0.007	0.007	0.007				
	Aloc Vers Gel	_	_	0.1	0.3	Moisturizer			
	Chamomile Extent		_	0.1	0.1	Skin Softener			
	Purple Fingrance Beads H&R A3050D	· -	0.5	_	0.5	Substantive Skin Fragmess and Visual			
15						Indicator			

Formula N and O were dispensed onto a wash cloth and spread over a wet forearm. Both products foamed and cleaned the skin. Formula O, with the purple fragrance beads provided a clear visual marker on the skin and were easily broken by rubbing them with the wash cloth.

To demonstrate the advantages of having a separate, skin substantive fragrance in a macro capsule bead, the following exportment was conducted with formulas P and Q. As octed in Table 7, the only difference between the two formulas is the 0.5% by weight of the violet bead containing the skin substantive fragrance H&R A 30550D which was different from the fragrance H&R A 30250R in the bulk product.

A test subject placed 15 g of Formula P on his moistened left arm and lathered the arm for 15 seconds with his hand. The arm was then thoroughly inseed for 60 seconds with 95° F. tepid water from a fast flowing faucet (1.5 to 2.0 gallons per minute). The arm was patted dry with an unperfurmed paper towel. In an identical fashion, 15 g of formula Q was applied to the right arm, lathered, rinsed and dried. The purple fragrance beads readily ruptured with hand pressure during lathering. After 15 minutes, one hour and four hours, independent evaluators were asked to smell the right and left forearm and rate each for residual fragrance intensity. The results are summarized in Table 8 below. To minimize any possible first smelled hist by the evaluators, alternate forearns were smelled first. Evaluators were allowed to rate one forearm more intense than the other or rate both forearms equal to fragrance intensity.

TABLE 8

Francisco Intensity on Treated Foresitt.							
SO Tuesc	:	No. of Evaluators		Q Formula More intense	No. Differences		
15 m	iπ.	5	0	4	3		
60 a	is.	3	0	3	0		
240	min.	3	0	3	Q		

After 15 minutes, one evaluator rated both arms equally intense, while four rated the one treated with Formula Q more intense. Subsequent longer time evaluation indicated the special skin substantive fragrance contained in Formula Q was always more intense.

The use of such macro bearls to deliver other cosmetic and medical treatments to the skin would be known to those skilled in the art.

The pump dispenser generally designated 30 in FIG. 3 is of known design and includes a saddle head 32 which can be pushed down with respect to a closure or cap 34, to raise a

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first ball valve 36 and move a piston 38 downwardly in a cylinder 40 which is connected to a container 42 for concylindra we want to connecte to a consister at its con-taining the loiton, gel or other viscous composition 44 according to the present invention. Downward pumping action is resisted by a return spring 46 which engages around a second ball valve 48 which rises to allow fluid from the container 42 to rise in an inductor tube 59, past valve 48 and spring 46 up through a hollow interior channel in piston 38, and through the interior of head 32 to be dispensed at 52. With the internal diameters of inductor 50 and piston 38 and the geometry of ball valves 36 and 48 selected so that the the geometry of ball valves 36 and 48 selected so that the fluid never passes through a constriction of less than the diameter of the largest beads in the composition, the beads will not reprare but will pass with the surrounding fluid in the direction of arrow 52. Conversely, if a pump dispenser is selected which has internal passages of smaller diameter, the beads will rupture allowing the contents of the beads to mix with the surrounding vehicle thus dispensing a colored mixture at 52.

FIG. 4 illustrates the conventional spray dispenser gen- 20 rit. 4 intestates the conventional syray dispenser gen-crally designated 60 which can also be used in accordance with the present invention for more fluid compositions which rise through a supply tube 62 during an initial primiting step when the trigger 64 is pumped a few times to discharge air from an outlet conduit 66 to fill the conduit with the air from an outlet conduit of to fill the conduit with the accomposition of the present invention. The composition is trapped in the passage 66 and its communicating passages, by a ball valve 68 and it dispensed by a prison 70 which is pushed invantly against the action of a rerum spring 72, to dispense fluid from passage 66 in the direction of arrow 74.

While specific embodiments of the invention have been shown and described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.
What is claimed is:

1. A flowable composition, comprising:

a carrier; and

visible friable beads disbursed in the carrier, the beads some trade occasion obsorbed in the carrier, the occasion containing an active ingredical and enclosing the active ingredient in a wall of bead material, the active ingre-dient amounting to approximately 0.5–5.0% by weight of the bead including its wall material and the active ingredient and including colorant in the wall material of the beads, the wall material being selected to be confriable when exposed to a process for mixing the beads with the carrier.

2. A composition according to claim 1 wherein the active ingredient comprises bactericidal liquid.

- 3. A composition according to claim 1 wherein the active ingredient comprises at least one essential fragrance oil.

 4. A composition according to claim 1 wherein the friable. beads are maintained in the carrier for at least about 24 to 48 hours before the composition is used.
- 5. A composition according to claim 4 wherein the beads are from about 500 to about 1,500 microns in diameter and the wall thickness of the beads is between about 210 and 740
- 6. A composition according to claim 5 wherein the active 60
- ingredient comprises intibacterial liquid.

 7. A composition according to claim 5 wherein the active ingredient comprises essential fragrance oils.

 8. A composition according to claim 1 wherein the carrier contains one fragrance and the active ingredient comprises a different fragrance.

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9. A composition according to claim 8 wherein the different fragrance in the beads is a skin activated essential fragrance oil, the fragrance in the carrier being a bulk

18. A composition according to claim 1 wherein the active ingredient is selected from the group consisting of fragrance, bestericidal liquid, a pharmaceutical, a skin moisturizer and a cleanser, the carrier having a different color from the colorant in the wall material of the beads and the beads amounting to between 0.5 and 10% by weight of the

11. A composition according to claim 10 wherein beads are from about 500 to about 1,500 microns in diameter and the wall thickness of the beads is between about 210 and 740

12. A method of treating a surface with an active ingredient comprising:

providing a carrier liquid:

dispersing in the carrier liquid a multiplicity of visible friable beads, each containing from about 0.5 to about 5.0% by weight active ingredients for treating the surface; and

massaging the carrier with beads onto the surface for massaging the cearier with beads onto the surface for rupturing the beads and discharging the active ingredient to mark the surface with ruptured beads.

13. A method according to claim 12 including providing colorant in the beads for smearing the colorant during rupturing of the beads.

14. A method according to claim 13 including providing activities the surface of the beads.

essential fragrant oils in the beads as the active ingredient.

15. A method according to claim L3 including providing anti-bacterial liquid as the active ingredient in the beads.

anti-bacterial liquid as the active ingredient in the beads.

16. A method according to claim 12 including providing the beads to have a diameter of about 500 to about 1,500 microns in diameter and the wall thickness of the beads is between about 210 and 740 microns.

17. A method according to claim 12 including maintaining the beads in the carrier liquid before massaging the carrier with beads to allow the beads to soften in the carrier.

18. A method according to the soften in the carrier.

18. A method according to claim 17 including maintaining the beads in the carrier before the massaging step for at least 24 hours.

19. A method of treating a surface with an active ingredient comprising:

providing a carrier liquid;

disbursing in the carrier liquid a multiplicity of visible friable beads, each containing from about 0.5 to about 5.0% by weight active ingredient for treating the sur-

dispensing the carrier with beads through a dispenser pump onto a surface; and

using the carrier with beads on the surface, at least one of the steps of dispensing or the step of using the beads on the surface, causing fracturing of the beads to spill their contents and mix it with the carrier liquid, the beads baving a different color from the carrier liquid to set as

having a different color from the carrier liquid to act as an indicator that the beads have ruptured.

20. A method according to claim 19 including dispensing the carrier liquid with beads through a pump having passages and geometry for rupturing the beads and mixing the active ingredients with the carrier liquid before the carrier liquid before the carrier liquid leaves the pump.

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March 30, 1998

VIA EXPRESS MAIL TB 35407 3885 US

Hiops

BOX PATENT APPLICATION Assistant Commissioner for Patents Washington, D.C. 20231

Re: U.S. Patent Application
For: LOTIONS AND GELS WITH ACTIVE
INGREDIENTS IN BEADS
Inventor: Ferguson, et al.
Our Ref. J25-277 US

Sir:

The above-identified patent application is transmitted herewith for filing.

Enclosed are:

- Patent Specification, Claims and Abstract consisting of 28 pages;
- Three (3) Sheets of Drawings containing Figs. 1-4; 2.
- Declaration and Power of Attorney; 3.
- Assignment with Cover Sheet for Recordal; and 4.
- Check in the amount of \$830.00.

STORED. SESESSES

Assistant Commissioner for Patents March 30, 1998 Page 2

Fees Calculation:

	Tot	al Fee	\$	830.00
Assignment:		41	0.00	40.00
Multiple Dependent Claims:		270.00/13	5.00	0.00
Total No. of Independent Claims:	(-3) =	ж 82.00/4	1.00	0.00
Total No. of Claims:	(-20) =	x 22.00/1	1.00	0.00
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Kindly acknowledge receipt of the above items by having your mail room stamp and return the enclosed postcard.

The Commissioner is hereby authorized to charge any fee under 37 CFR 1.16 and 1.17 which may be required during the entire pendency of the application to Deposit Account No. 14-1431.

Dated: March 30, 1998

Respectfully submitted,

Peter C. Michałos Attorney for Applicant Reg. No. 28,643 (212) 564-0200

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RECERC. DESCENCE

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Patent J25-277

LOTIONS AND GELS WITH ACTIVE INGREDIENTS IN BEADS

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates, in general, to skin care and household products, and in particular, to a new and useful gel or lotion which can be used for such things as sanitizing the hands, moisturizing and adding fragrance to the skin, a shampoo, a liquid soap product, a household cleanser and the like, which includes active ingredients such as antibacterial agents or essential oils, which are captured within friable beads.

The use of microencapsulation is known in various fields. Microencapsulation involves the capturing of active ingredients within a shell which can be broken or dissolved, depending on the environment in which the active ingredient is to be released. Generally, however, microencapsulation has been utilized in the pharmaceutical and quasi-pharmaceutical field, to time release medication, vitamins or minerals by encapsulating the active ingredient within a shell which dissolves over time in the stomach.

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The use of encapsulated materials to control release and improve the stability of composition is well established. Encapsulation efficiency can be improved by reducing the relative percentage of the protective wall material and increasing the quantity of the core encapsulate. Emphasis has been place on maximizing the absolute delivery of the encapsulated core material. The present invention teaches the use of macro capsules (500-1,500 microns) as a way to visually mark the coverage of personal care, household and pharmaceutical preparations. Further, this invention teaches a very low concentration of core material (0.5% to 5.0%) is an effective way to provide controlled release and visual indication of product coverage, which is contrary to general teaching in this field. The present invention can also be used to mix incompatible, quasi-compatible or complimentary ingredient (carrier formula and beads contents) at the time of

SUMMARY OF THE INVENTION

An object of the present invention is to take advantage of rupturable beads in a liquid gel or lotion, which contain small amounts of active ingredients for use in cleansing, treating or adding fragrance to the skin of a user or for other household uses.

According to the present invention, the beads may contain either an antiseptic such as Triclosan, or essential fragrance oils, referred to as essential oils, for imparting fragrance and/or other active ingredients to the skin such as moisturizers and the like, or as cleansers for other surfaces.

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It was found by the inventors that the use of beads which were too flexible would allow the beads to survive the manufacturing process, but the beads would not then readily break when the lotion or gel was rubbed onto the skin. One hurdle which was overcome by the present invention was to utilize beads of proper diameter and wall thickness which did not rupture during the manufacturing process, but, after a 24 to 48 hour induction period were friable (pulverizable or rupturable) when the lotion or gel was rubbed onto the skin or dispensed through a restrictive orfice. It was found that beads that contained only about 0.5 to about 5% by weight active ingredient and which are mostly wall material, could be used according to the present invention and in fact, added an additional advantage in that the wall material could contain coloring which would act as an indicator to the user both that enough of the active ingredient was present on the hands or surface and secondly, that the active ingredient has been released in that the color would smear, indicating rupturing of the beads.

The use of beads also permitted the inventor to utilize a dual fragrance system. One fragrance is in the carrier lotion which carries the beads. This fragrance is tailored to be pleasant when exposed to the air. Another different fragrance, however, was used with the active ingredient in the beads, in particular, in the version of the invention for This different dispensing essential oils to the skin. fragrance was selected both to give a different scent, but also to be of the type of fragrance which is best activating when coming into contact with the skin. It is known in the field of fragrances that some fragrances are more effective as "room fresheners" and others are more effective as "perfumes"

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in that they are more active and have different advantageous effects when applied to the skin. By providing the active ingredient with the skin compatible fragrance in the beads, two separate fragrances could be utilized in the product, and fragrances which were tailored for their particular use, that is, either to give out a fragrance simply upon contact with the air or to give out a fragrance best when in contact with the skin.

The lotion and gels of the present invention whether for containing the essential oils or the antibacterial agent, have preferred approximate diameters of about 500 to 900 microns with a wall thickness of about 210 to 440 microns.

Compositions in the form of a shower gel containing beads with essential oils, are generally about 1000 to 1500 microns in diameter with a wall thickness of about 460 to about 740 microns.

Despite the relatively small volume within the bead wall, which is available for containing the antibacterial agent or essential oil at a rate of only about 0.5 to about 5% by weight of the overall bead, sufficient active ingredient is present to satisfy the purpose of the invention and also to add the indicating function and provide sufficiently robust beads. Accordingly, the seeming disadvantage of having beads with very large wall thicknesses, is more than compensated by the other advantages of indication and friability characteristics.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses,

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reference is made to the accompanying drawings and descriptive matter in which a preferred embodiment of the invention is illustrated.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-sectional view of a bead for containing an active ingredient and for use in a lotion composition of the present invention;

Fig. 2 is a view similar to Fig. 1 of another embodiment of the bead for use with a gel of the present invention;

Fig. 3 is a schematic sectional view of a dispenser for lotions and gels which can be used to dispense the composition of the present invention and to practice the method of the present invention; and

Fig. 4 is a schematic sectional view of a sprayer mechanism which can also be used to dispense the composition of the present invention and in accordance with the method of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, Fig. 1 illustrates a bead generally designated 10 in accordance with the present invention having a diameter D1 of about 500 to 900 microns and a wall thickness W1 of about 210 to 445 microns. Although these measurements are approximations, they are representative and illustrate the fact that bead 10 is mostly wall thickness

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with only a very small, roughly spherical volume 12 remaining to contain the active ingredients whether it is the antibacterial agent or the essential oils of the present invention. By weight, bead 10 is about 98 to 99.5% wall material and only about 0.5 to about 2% active ingredient in volume 12.

These dimensions are representative for the beads used in the lotions of the present invention, both the essential oil containing lotion referred to as an "Aromatherapy" lotion, and an antibacterial lotion containing Triclosan or other antibacterial agent.

Fig. 2 illustrates a bead generally designated 20 useful in gels of the present invention such as shower gels and shampoo gels. In this embodiment, the diameter D2 is about 1000 to 1500 microns and the wall thickness W2 is about 420 to 740 microns. This also leaves a volume 22 for containing only about 0.5 to about 5.0% by weight active ingredient, the bead being mostly inert wall material.

Although intuitively, this would appear to be a disadvantage in that very small amounts of active ingredients are present, in fact, the thick walls of the beads compensate any disadvantages by providing the advantages of dual fragrance capabilities and beads which are not friable during the manufacturing process involving mixing together and loading of the lotions or gels into bottles. The beads, after a 24 to 48 hour introduction period, do become friable when they are massaged into the skin or scalp, however, causing the beads to break and thus releasing their active ingredients in sufficient quantities to have the desired effects. addition, the wall material can contain a harmless non-toxic colorant which is water soluble or water disbursable and which adds to the effect of the invention by providing a visual que to the amount of active ingredient being worked into the skin and also the fact that sufficient mechanical massaging has taken place to activate the ingredients by rupturing the beads and smearing to color. The beads, in effect, rupture and smear across the skin, releasing the active ingredient. The bead material is easily washed away with water, however, so that no adverse effect occurs. For example, a white, yellow or pink translucent or clear lotion or gel may contain blue or green color beads.

Another use of the invention involved a hydro alcoholic solution capable of dispensing a fragrance or providing an effective disinfective alcohol concentration to the skin or a hard surface. In this application, the encapsulated bead breaks inside the pump mechanism, intimately mixing and coloring the solution. Thus a clear solution with colored beads dispensed throughout can be dispensed onto the skin as a colored product. This can be used for both aesthetic purposes and functionally to mark product placement on the skin or some other surface.

An example of the shower gel has the following approximate composition and range of amounts:

Table 1

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Ingredient	Representative Amount	Range
Water	45	35-70
Thickener	1.2	0.5-5
Surfactant	36	12-40
Fragrance	2	0.5-3
Emollient	2	0.5-5

An example of a lotion according to the present invention is:

i	9	O	Χ		
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Table 2

Ingredient	Representative Amount	Range
Water	80	40-9D
Emulsifier	4	3-10
Emollient	10.75	2-10
Botanicals	0.7	0.1-1
Fragrance	1.0	0.2-3
Triclosan	0.3	0.1-1

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In the lotion, the beads amount to approximately 0.5 to 2.0% by weight of the overall composition and in the gel, the beads amount to 0.5 to 1.0% of weight of the overall composition.

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To be effective, the wall material must be colored and possess sufficient strength to withstand normal manufacturing mixing, pumping and filling operations. In use, the wall material must be friable enough to break easily with hand pressure or implement (cloth, sponge or paper) wiping.

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Ideally, the macro capsule should have an impervious wall material in the dry state and gradually soften in the cleaning, cosmetic or pharmaceutical preparation. characteristic allows the capsules to be processed fresh, in a hardened state, and become friable when equilibrium is established with the preparation.

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Capsule breakage can be accomplished by hand or implement pressure after the preparation has been dispensed. It can

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also be fractured at the time of application by dispensing the preparation through a mechanical pump or restricted orifice. This latter technique allows the colored wall material and its encapsulate core to intimately mix with the preparation at the precise moment of use. The resultant product is colored and provides strong visual indication of its coverage.

If the internal clearances of the pump are smaller than the D1 or the D2 in Figs. 1 and 2 herein, the cross sectional diameter of the bead, it will rupture inside the pump and intimately mix with the rest of the formula. This could lead to the mixing of two quasi-compatible or incompatible ingredients (formula and bead) to produce neutralization, heat, color or some other chemical reaction.

After the beads are placed in solution (aqueous or hydroalcoholic) the wall slowly softens and becomes friable. This induction period is dependent upon time, temperature and the surface activity of the formula. For the examples, this induction period is 24 to 48 hours at room temperature.

The following examples demonstrate the utility of the invention across three broad product categories: pharmaceutical, personal care and cleaners. These examples also demonstrate the importance of the induction period to produce friability. Finally, the examples demonstrate the bead release mechanics, via hand or implement wiping and internal breakage, via mechanical dispensing.

In all of the applications cited, the 500 to 1500 microns (31 thousandths to 58 thousandths of an inch) cellulose, lactose, hydroxypropyl methyl cellulose spherical macro beads identified by the trademark UNISPHERES manufactured by Induchen AG of Dubendorf, Switzerland and with the generalized formula listed below were added to the formula last. The



Table 3

Generalized Bead Composition

-	10	Mate	rial					% by	weig	<u>ht</u>		
			ulose	юруі	Methy	l Cel	ļulos	e	·} } }	98		
의 기 기	15	Colo Perf		or tri	closa	n		•		2		
iji •										100		
1 E	JIX ·	Tabl	<u>e 4</u>									
□ □		<u>Anti</u>	-Bact	erial	Wate	r in	011 L	otion	Form	ulas		
ක ත	20 <u>Mater</u>	<u>cial</u>	A	В	С	D	E	F .	·G	н	I	Function
	Water	:	QS	QS	QS	QS	QS	QS	QS	QS	Qs	Carrier
	Tricl	osan	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	Biocide
	Glyce	rin	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	Humectant
	Stear	ric A	cid3.	0 3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	Emulsifier
	25Triet	hano.	1									
	Amine	•	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	3.0	Neutralizer
•	Cetyl	•	•									
	Alcoh	ol			0.75	0.75	0.75	0.75	0.75	0.75	0.75	Emulsifier
	Glyco	1										

3.5 3.5 3.5 3.5 3.5 3.5 Emollient Dimethicone ____ 0.25 0.25 0.25 0.25 0.25 0.25 0.25 Occlusive 0.4 0.4 0.4 Conditioning Wheat Germ Oil _____ 0.4 0.4 0.4 Agent Panthenol ____ _ _ _ 0.1 0.1 0.1 0.1 0.1 Conditioning Agent Perfume, Apple __ _ _ _ _ 1.0 1.0 1.0 Fragrance Colorant F, D, & C Yellow 6 _____ _ 0.001 Blue Beads __ 1.0 ___ 1.0 ___ 0.5 __ 0.75 1.0 Biocide, Visual Indicator 100 100 100 100 100 100 100 100 100 15 Examples A through H (Pharmaceutical Application): Various triclosan containing anti bacterial oil in water emulsion were prepared by dispensing an aqueous phase into the oil phase and mixing until uniform. Color, fragrance, and skin conditioning agents were added to modify the preparation for various applications. The product in example A is an opaque white emulsion. When applied to the skin it is difficult to visually gauge product coverage. Product from example B, containing the lactose-cellulose beads was placed in a tube and in two 8 cz. 25 PVC plastic bottles fitted with commercially available dispensers, one of which is Fig. 3. This and other suitable dispensers are available from Calmar Inc. of City of Industry,

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Within an hour of preparation and filling, it was attempted to dispense Example B from another lotion pump dispenser with small complex internal passages. The beads quickly clogged the dispenser and product could not be dispensed. Product B was also dispensed form the bottle using the high volume of Fig. 3 pump. This time the product dispensed easily and the individual blue beads were readily observed in the white lotion. However, like the Product B dispensed from a tube, the beads were hard and could not be broken by hand rubbing.

Product or Example B was then allowed to remain at room temperature for 48 hours. After this induction period, product dispensed from the tube quickly broke under hand pressure. The presence of the blue colored beads clearly marked where the lotion had been dispensed. When the lotion was spread onto the skin, the hand pressure caused the blue colored beads to quickly break citing a trail of color which designated to the user product coverage. As the lotion was the blue dissipated and left no rubbed into the skin, recognizable color on the skin.

In a similar fashion, after 48 hours at room temperature, the product in Product B was dispensed through each of the two Calmar dispensers previously described. The results are described below. The pump of Fig. 3 is a high volume pump (0.8 to 1.2g per actuation) and has internal tolerances greater than be cross-sectional diameter of the bead. That is the blue beads passed through the pump mechanism without breaking and was dispensed onto the skin as a white lotion with discrete blue beads dispensed throughout, As with the product dispensed form the tube, the white lotion with blue beads quickly broke with hand pressure, marked where the

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lotion had been, quickly faded away leaving recognizable color.

The other Calmar pump (a model MD-150) is a low volume pump (0.10 to 0.25 g per actuation) with internal tolerances smaller than the cross-sectional diameter of the beads. When dispensed, the internal pump mechanism in the MD-150 broke the beads, mixed them with the dispersed phase and the product exited the pump as a light blue homogeneous lotion. That is, the blue beads broke inside the pump at the discharge valve inside the spin chamber and mixed into the white lotion to produce a single-phase light blue lotion. The light blue lotion was easily discernable on the skin and quickly dissipated as it was rubbed into the skin. In a similar fashion, the product example pairs described by C/D, E/F and G/H behaved in the same fashion. The white lotions in C, E and G were functional but did not provide the user with a clear indication of product location or coverage. The white lotion with blue beads; D, F and H, after a 48 hour induction period, could be dispensed as an intack discrete two component system through a tube or a mechanical pump; e.g. the Calmar pump of Fig. 3 whose internal pumping tolerances or final restriction metering orifices were greater than the crosssectional diameter of the beads. If the pump tolerances of final metering orifices were less than the cross-sectional lead diameter, the blue Triclosan beads broke and thoroughly mixed together to produce a homogenous single light blue The color of lotion could be easily adjusted by varying the concentration of blue Triclosan beads in the final formula. The higher the bead concentration, the more intense the homogeneous blue color.

This discovery also permits the preparation of two chemically incompatible ingredients to exist together in either the continuous lotion phase or dispersed bead phase. To demonstrate this, a small amount of F, D & C Yellow No. 6 was added to preparation H to produce Example I, a light yellow lotion with blue beads. When dispensed from a tube or a bottle fitted with a Fig. 3 pump, after the 48-hour induction period, the user could readily observe on the skin a light yellow lotion with blue Triclosan beads. This turned into a light green lotion as the hand pressure broke the beads and the blue and yellow mixed together. If a Calmar MD-150 pump is used, the light yellow lotion with blue Triclosan beads in the bottle will dispense as a homogenous light green lotion because the internal pump mechanism will beak the blue beads and thoroughly mix them with the yellow lotion.

To further demonstrate the utility of this invention, the following examples are listed in Table 5 below. In all cases the beads were added to formula G for 24 to 48 hours before the experiment was conducted.

Table 5

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Anti Bacterial Oil in Water Lotion Formulas Encapsulated Bead Color Dispensing Options

	Experiment	Appearance Before Dispersing	Calmar Dispenser	Appearance After Dispensing
25	1. Pormula G + 1% blue beads	White Lotion with Blue Beads	MD-150	Uniform Light Blue Lotion
30	2. Formula G 6% blue beads	+ White Lotion with Blue Beads	MD-150	Uniform Dark Blue Lotion

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	Blue and yellow eads beads		Uniform medium Green Lotion
4. Formula G + 1% blue beads	White lotion with purple beads	MD-150	Uniform medium Purple Lotion
5. Pormula I	Yellow Lotion with Blue Speckles	MD-150	Uniform medium Green Lotion
6. Formula I	Yellow Lotion with Blue Speckles	Fig. 3	Yellow lotion with Blue Speckles which Formed a Medium Green Lotion When Rubbed into the Skin.

Formula C + 19 White lotion with

These experiments indicate a wide variety of colors and intensities can be created by either dispersing the appropriate concentration of colored beads in a white lotion or adding the appropriate concentration of colored beads to a colored lotion. The color can be created by fracturing the friable beads in the internal mechanical dispensing device when the pump tolerances are smaller than the cross sectional bead diameter. Alternately, the color can be created in situ on the skin or other hard surface by dispensing the preparation through a tube or mechanical dispenser with internal metering tolerances greater than the cross sectional bead diameter.

Those skilled in the art would readily recognize this discovery is also applicable to encapsulating one or more chemically reactive species within a bead and uniformly mixing the ingredient into the preparation at either the moment of mechanical dispensing or upon hand and/or implement pressure as the preparation is rubbed into the skin.

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In each of the foregoing formulas and experiments, the presence of the colored ultramarine blue beads containing the triclosan active provided the user with a visible marker that the antibacterial preparation was being correctly and uniformly applied to the treated area. This is especially helpful to users where under application could create secondary infection or over application could create undue . surrounding tissue trauma.

This invention is also applicable to other uses such as disinfecting hand surface cleansers and personal care products where visible indication of product coverage or specialized encapsulation of ingredients are important for performance and functionality.

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Table 6

Disinfecting Hard Surface Cleaner Formulas Percent by Weight

<u>Material</u>	J	K	L	M	Function
Ethyl Alcohol	65	65	65	65	Anti Microbal
Water	QS	QS	QS	QS	Solvent
Diisopropyl Amine	0.5	0.5	0.5	0.5	Neutralizer
Carbopol 941	0.35	0.35	0.35	0.35	Thickening/ Suspending Agent
Aloe Vera Gel	·		0.5	0.5	Moisturizer
Perfume. Apple			1.0	1.0	Fragrance

Ultramarine Blue
Triclosan Beads ___ 0.5 __ 1.0 Biocide, Visual
___ __ ___
100 100 100 100 Indicator

Formulas J through M are transparent, thickened, alcohol gels with viscosities of 5,000 to 8,000 cps. Formulas J and K are suitable hard surface disinfectant formulas suitable for kitchen and other food contact sanitization applications. They are also disinfectant products for bathroom and other hard surface articles such as doorknobs, shopping cart handles and telephone receivers. The formulas were made by dispensing the Carbopol 941 into water, neutralizing it with disopropylamine and adding the alcohol. Perfume moisturizer and/or Triclosan beads were subsequently added.

The triclosan containing blue beads were added to formulas K and M and used within 30 minutes of preparation and after a 24 hour induction period. Formula K was dispensed with a trigger spray pump fabricated with a transparent plastic housing as shown in Fig. 4. This device was chosen because the blue beads could be visually observed during the dispensing operation.

Formula J, when sprayed onto a white enameled surface, was difficult to visually observe for coverage. Ultramarine blue triclosan beads were added to produce Formula K. When sprayed through the trigger spray pump within thirty minutes of preparation the pump quickly clogged. Visual inspection of transparent pump mechanism revealed the beads had become lodged in both the dip tube leading to the piston chamber and

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Both areas were full of in the piston chamber itself. unbroken beads, rendering the pump nonfunctional. After 24 hours, Formula K was transferred to a new bottle and a new trigger spray pump of Fig. 4 was attached to the bottle. The formula easily dispensed through the pump. Visual inspection of the pump indicated the piston chamber contained a clear light blue homogenous solution indicating the clear continuous phase of the alcohol sanitizer had thoroughly mixed with the ultramarine triclosan beads. When sprayed onto a white enameled surface; a light blue solution was readily observed. This light blue solution was easily wiped away with a paper towel yielding a clean, disinfected surface.

Formula L an instant hand sanitizer, was poured onto the hands and rubbed into the skin. Product coverage was difficult to observe. Formula M was poured onto the hands A clear alcohol gel within 30 minutes of preparation. containing bright blue speckles was readily observed. The formula when rubbed into the hands, was very uncomfortable. The beads were hard and granular and could not be broken with hand pressure. After 24 hours, Formula M was poured into the hands. The transparent alcohol gel containing blue speckles easily fractured with hand pressure marking where the product had been applied. The formula easily rubbed into the hands and left no observable color.

Formulas N through Q are transparent, thickened, surfactant cleaning solution with viscosities of 8,000 to previous examples, Aв the in 20,000 cps. lactose/cellulose beads described in Table 3 required a 24 to 48 hour induction period before the beads became friable and easily broken by mechanical, hand or implement pressure. The colored lactose/cellulose beads used in Formulas O and Q contained a 100% active perfume oil specifically designed to be substantive to the skin. This encapsulated oil was different from the bulk fragrance in the shower gel. Bulk fragrances must be specifically formulated to be compatible with the preparation. They are incorporated into the final product with solvents or emulsifiers to yield homogenous solutions or dispersions. Since most of the perfume will be either rinsed, wiped or washed away, it is a very inefficient process to directly apply perfume to an absorbent substrate such as skin and retain lasting fragrance benefit from the absorbed perfume. Furthermore, the only fragrance effect that can be created is that fragrance which comes from the bulk perfume in the formula.

The examples listed in Table 7 demonstrate the ability to formulate a dual fragrance personal care product. invention permits the user to experience both the fragrance from the bulk product during the shower or bathing activity and the same or different fragrance directly apply to the skin from a friable encapsulated fragrance bead. This produces a longer lasting fragrance benefit.

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Table 7

Bath and Shower Formulas Percent by Weight

	Material	N	0	P	Q	<u>Function</u>
25	TEA Laurel Sulfate	18.0	18.0	18.0	18.0	Surfactant
	Water	QS	QS	QS	QS	Solvent
	Carbopol 2020	1.2	1.2	1.2	1.2	Thickener
	Carboxtmethylcellul	Suspending Agent				

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Triethanol Amine	1.3	1.3	1.3	1.3	Neutralizer
Propylene Glycol	5.0	5.0	5.0	5.0	Rheology Control
Ethyl Alcohol	4.0	4.0	4.0	4.0	Rheology Control
Carbowax 400	0.9	0.9	0.9	0.9	Emulsifier
Citric Acid	0.1	0.1	0.1	0.1	pH Control
Silicone Fluid	2.0	2.0	2.0	2.0	Moisturizer
Germaben II	1.0	1.0	1.0	1.0	Preservative
Fragrance: H&RA3025OR	2.0	2.0	2.0	2.0	Perfume
D&C Violet #2	0.00	7 0.0	07 0.	007 0.007	Colorant
Aloe Vera Gel			0.1	0.I .	Moisturizer
Chamomile Extract			0.1	0.1	Skin Softener
Purple Fragrance Beads H&R A3050D		0.5	<u></u>	0.5	Substantive Skin Fragrance and Visual Indicator

Formula N and O were dispensed onto a wash cloth and spread over a wet forearm. Both products foamed and cleaned the skin. Formula O, with the purple fragrance beads provided a clear visual marker on the skin and were easily broken by rubbing them with the wash cloth.

To demonstrate the advantages of having a separate, skin substantive fragrance in a macro capsule bead, the following experiment was conducted with formulas P and Q. As noted in Table 7, the only difference between the two formulas is the 0.5% by weight of the violet bead containing the skin substantive fragrance Har A 30550D which was different from the fragrance H&R A 30250R in the bulk product.

A test subject placed 15 g of Formula P on his moistened

left arm and lathered the arm for 15 seconds with his hand. The arm was then thoroughly rinsed for 60 seconds with 95°F tepid water from a fast flowing faucet (1.5 to 2.0 gallons per minute). The arm was patted dry with an unperfumed paper towel. In an identical fashion, 15g of formula Q was applied to the right arm, lathered, rinsed and dried. The purple fragrance beads readily ruptured with hand pressure during 'After 15 minutes, one hour and four hours, independent evaluators were asked to smell the right and left forearm and rate each for residual fragrance intensity. The results are summarized in Table 8 below. To minimize any possible first smelled bias by the evaluators, alternate forearms were smelled first. Evaluators were allowed to rate one forearm more intense than the other or rate both forearms equal in fragrance intensity.

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Table 8 Fragrance Intensity on Treated Porearm

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Time No. of Evaluators	P Formula More Intense	O Formula More Intense	No. Differences
15 min. 5	0	· 4	1
60 min. 3	0	3	0
240 min. 3	0	3	0

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After 15 minutes, one evaluator rated both arms equally intense, while four rated the one treated with Subsequent longer time Formula Q more intense. evaluation indicated the special skin substantive fragrance contained in Formula Q was always more intense.



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The use of such macro beads to deliver other cosmetic and medical treatments to the skin would be known to those skilled in the art.

The pump dispenser generally designated 30 in Fig. 3 is of known design and includes a saddle head 32 which can be pushed down with respect to a closure or cap 34, to raise a first ball valve 36 and move a piston 38 downwardly in a cylinder 40 which is connected to a container 42 for containing the lotion, gel or other viscous composition 44 according to the present Downward pumping action is resisted by a invention. return spring 45 which engages around a second ball valve 48 which rises to allow fluid from the container 42 to rise in an inductor tube 50, past valve 48 and spring 46 up through a hollow interior channel in piston 38, and through the interior of head 32 to be dispensed at 52. With the internal diameters of inductor 50 and piston 38 and the geometry of ball valves 36 and 48 selected so that the fluid never passes through a constriction of less than the diameter of the largest beads in the composition, the beads will not rupture but will pass with the surrounding fluid in the direction of arrow 52. Conversely, if a pump dispenser is selected which has internal passages of smaller diameter, the beads will rupture allowing the contents of the beads to mix with the surrounding vehicle thus dispensing a colored mixture at 52.

Fig. 4 illustrates the conventional spray dispenser generally designated 60 which can also be used in accordance with the present invention for more fluid compositions which rise through a supply tube 62 during

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an initial priming step when the trigger 64 is pumped a few times to discharge air from an outlet conduit 56 to fill the conduit with the composition of the present invention. The composition is trapped in the passage 66 and its communicating passages, by a ball valve 68 and is dispensed by a piston 70 which is pushed inwardly against the action of a return spring 72, to dispense fluid from passage 66 in the direction of arrow 74.

while specific embodiments of the invention have been shown and described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.

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WHAT IS CLAIMED IS:

A flowable composition, comprising:

- a carrier; and Virtuable beads disbursed in the carrier, the beads containing an active ingredient and enclosing the active ingredient in a wall of bead material, the active ingredient amounting to approximately 0.5 - 5.0% by weight of the bead including its wall material and the active ingredient and including colorant in the wall material of the beads, the wall material being selected to be non-friable when exposed to a process for mixing the beads with the carrier.
- A composition according to claim 1 wherein the active ingredient comprises bactericidal liquid.
- 3. A composition according to claim I wherein the active ingredient comprises at least one essential fragrance oil.
- A composition according to claim 1 wherein the friable beads are maintained in the carrier for at least about 24 to 48 hours before the composition is used.
- A composition according to claim 4 wherein the beads are from about 500 to about 1,500 microns in diameter and the wall thickness of the beads is between about 210 and 740 microns.

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- A composition according to claim 5 wherein the active ingredient comprises antibacterial liquid.
- A composition according to claim 5 wherein the active ingredient comprises essential fragrance oils.
- A composition according to claim 1 wherein the carrier contains one fragrance and the active ingredient comprises a different fragrance.
 - A composition according to claim 8 wherein the different fragrance in the beads is a skin activated essential fragrance oil, the fragrance in the carrier being a bulk fragrance.
 - 10. A composition according to claim 1 wherein the active ingredient is selected from the group consisting of fragrance, bactericidal liquid, a pharmaceutical, a skin moisturizer and a cleanser, the carrier having a different color from the colorant in the wall material of the beads and the beads amounting to between 0.5 and 10% by weight of the composition.
- 11. A composition according to claim 10 wherein beads 20 are from about 500 to about 1,500 microns in diameter and the wall thickness of the beads is between about 210 and 740 microns.
 - 12. A method of treating a surface with an active ingredient comprising:
 - providing a carrier liquid;

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indispersing in the carrier liquid a multiplicity of friable beads, each containing from about 0.5 to about 5.0% by weight active ingredients for treating the surface; and

massaging the carrier with beads onto the surface for rupturing the beads and discharging the active ingredient to mark the surface with ruptured beads.

- 13. A method according to claim 12 including providing colorant in the beads for smearing the colorant during rupturing of the beads.
- 14. A method according to claim 13 including providing essential fragrant oils in the beads as the active ingredient.
- 15. A method according to claims 13 and 14 including providing anti-bacterial liquid as the active ingredient in the beads.
- 16. A method according to claim 12 including providing the beads to have a diameter of about 500 to about 1,500 microns in diameter and the wall thickness of the beads is between about 210 and 740 microns.
- 17. A method according to claim 12 including maintaining the beads in the carrier liquid before massaging the carrier with beads to allow the beads to soften in the carrier.

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- 18. A method according to claim 17 including maintaining the beads in the carrier before the massaging step for at least 24 hours.
- 19. A method of treating a surface with an active ingredient comprising:

providing a carrier liquid;

disbursing in the carrier liquid a multiplicity of viriable beads, each containing from about 0.5 to about 5.0% by weight active ingredient for treating the surface;

, dispensing the carrier with beads dispenser pump onto a surface; and

using the carrier with beads on the surface, at least one of the steps of dispensing or the step of using the beads on the surface, causing fracturing of the beads to spill their contents and mix it with the carrier liquid, the beads having a different color from the carrier liquid to act as an indicator that the beads have ruptured.

20. A method according to claim 19 including dispensing the carrier liquid with beads through a pump having passages and geometry for rupturing the beads and mixing the active ingredients with the carrier liquid before the carrier liquid leaves the pump.

ABSTRACT OF THE DISCLOSURE

A flowable personal care or fleaning composition, comprising a carrier and friable beads disbursed in the carrier, the beads containing an active ingredient and enclosing the active ingredient in a wall of bead Ingredient amounting to material, the active approximately 0.5 - 5.0% by weight of the bead including its wall material and the active ingredient.

pocket No.J25-277 US

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled LOTIONS AND GELS WITH ACTIVE INGREDIENTS IN BEADS
the specification of which

(check one)

[x]	is attached hereto was filed on		_as
. ,	Application Serial No and was amended on	o	
	and was amended on _		
		(it applicable)	

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, \$119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

Yes No

(Number) (Country) (Day/Month/Year Filed) [] []

(Number) (Country) (Day/Month/Year Filed) [] []

(Number) (Country) (Day/Month/Year Filed) [] []

I hereby claim the benefit under Title 35, United States Code, \$120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, \$112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, \$1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Serial No.) (Filing Date) (Status) (patented, pending, abandoned)

(Application Serial No.) (Filing Date) (Status) (patented, pending, abandoned)

Page 2

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Angelo Notaro Reg. No. 27,664

Peter C.Michalos Mark A. Conklin Reg. No. 28,643 Reg. No. 39,148

John Zaccaria Reg. No. 40,241

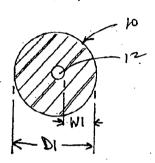
Send Correspondence to: NOTARO & MICHALOS P.C.
Empire State Building
350 Fifth Avenue, Suite 6902
New York, New York 10118-8985

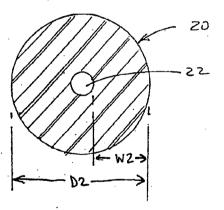
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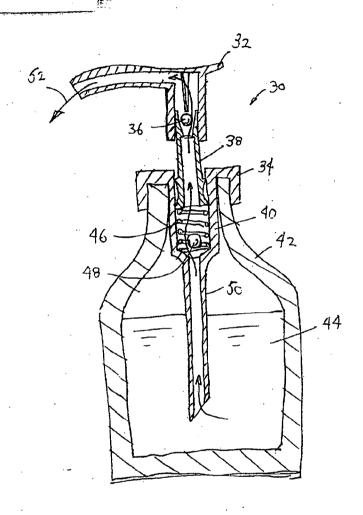
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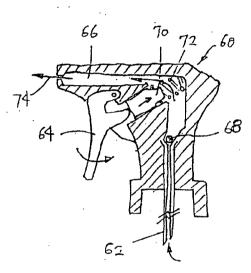
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UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO. | . FILING DATE | 09/050,536 | 03/30/98 FIRST NAMED INVENTOR J25-277-US HM22/0702 EXAMINER ٠ ـ ٦ NOTARO & MICHALOS EMPIRE STATE BUILDING 350 FIFTH AVENUE SUITE 6902 NEW YORK NY 10118-6985 SPEAR, J ART UNIT PAPER NUMBER 1615 07/02/99 DAYE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

« · · · Commissioner of Patente and Trademarks

	Application No. 09/050,536	Applicant(s	FERGUSON,	ET AL.
Office Action Summary	Examiner JAMES M. S	PEAR	Group Art Unit 1615	
IX Responsive to communication(s) filed on Mer 30,	1998			
☐ This action is FINAL.				
Since this application is in condition for allowance in accordance with the practice under Ex parte Out			on as to the me	rits is closed
A shortened statutory period for response to this acti is longer, from the mailing date of this communication application to become abandoned. (35 U.S.C. § 133 37 CFR 1.136(a).	n. Failure to respond with	in the perio	d for response	will cause the
Disposition of Claims				
		is/are	pending in the	application.
		• •		30,10,100,100,11
☑ Claim(s) 1-19			s/are rejected.	
☑ Cleim(s) 20	ere subjec		s/are objected t	
Claims	ase subjec	t to restric	tion or siection i	requirement.
The drawing(s) filed on	is Lap r. aminer. in priority under 35 U.S.C 0 copies of the priority do (Serial Number) - from the International Bu	proved [. § 119(e)- cuments ha	(d). ve been Rule 17.2(e)).	· ·
☐ Interview Summary, PTO-413	, reper Noist	*		
Notice of Draftsperson's Patent Drawing Review	v, FTO-948	•		
☐ Notice of Informal Patent Application, PTO-152	· 1.			
	• •			
• •				;
SEE OFFICE AC	TION ON THE FOLLOWING	PAGES		
S. Pacent and Trademark Office	on Acting Summons			

Art Unit: 1615

Page 2

Claim 15 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al. U.S. 5,089,269.

For claim 1, see examples 1-2, 2-3, 2-7, claim 1 of Noda et al. The reference shows active ingredients including drugs which would encompass bactericidal liquids and fragrance oils. See column 14, lines 3-12. The capsules are stable and

Page 3

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can be maintained in a carrier for at least about 24-48 hours. See column 20, line 60 through column 21, line 68. The examples further show the use of various colorants. See example 4-4. The skilled artisan would immediately envision minor modifications relating to carriers and containers for dispensing the carrier with beads. Cosmetic lotions/solutions by definition are considered to encompass pump dispensers. In describing the variety of suitable cosmetics the equivalent cosmetically acceptable containers, though not explicitly described, would be envisioned by one skilled in the art.

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Spear whose telephone number is (703) 308-2457. The examiner can normally be reached on Monday thru Friday from 6:30 A.M. to 3:00 P.M.

Art Unit: 1615

Page 4

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-3592 or 308-4556.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Page 5

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

James M. Spear

June 30, 1999

A B B C C C C C C C C C C C C C C C C C	DOCUMENT NO. 5,089,209	DATE 02/18/92	Examinor JAMES M. S S. PATENT DOCUMENTS NAME NODA, E	:	Group Art Unit	P. CLASS 424	SUBCIASS 450
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PORM PTO 948 (REV. 11-97)

U.S. DEPARTMENT OF COMMERCE-Patent and Trademark Office

NOTICE OF DRAFTPERSON'S PATENT DRAWING REVIEW

wings who necessary. Corrected drawings must be submitted according to the	indicated below. The Examiner will require submission of new, corrected
	astractions on the back of this police.
DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:	7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3)
Black ink. Color.	Heaching not indicated for sectional portions of an object.
Color drawing are not acceptable until petition is granted.	Fig.(s)
Fig.(s)	Sectional designation should be noted with Arabic or
Pencil and non black ink is not permitted. Fig(s)	Roman numbers. Fig.(s)
PHOTOGRAPHS. 37 CFR 1.84(b)	8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
Photographs are not acceptable until petition is granted,	Words do not appear on a horizontal, left-to-right fashion when
3 full-tone sets are required. Fig(s)	page is either upright or rumed, so that the top becomes the right
Photographs not properly mounted (must brystol board or	side, except for graphs. Fig.(s)
photographic double-weight paper). Fig(s)	Views not on the same plane on drawing sheet. Fig.(s)
Poor quality (half-tone). Fig(s)	9. SCALE 37 CFR 1.84(k)
TYPE OF PAPER. 37 CFR 1.84(e)	Scale not large enough to show mechansim without crowding
Paper not flexible, strong, white and durable.	when drawing is reduced in size to two-thirds in reproduction.
Fig.(s)	Fig.(s)
Ensures, alterations, overwritings, interlineations, folds, copy machine marks not acceptable. (100 thin)	WE CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(I)
Mylar, vellum paper is not acceptable (too thin).	Lines, numbers & letters not uniformly thick and well defined.
	clean, durable and black (poor line quality).
Fig(s)	Fig.(s)
	11. SHADING. 37 CFR 1.84(m)
21.0 cm by 29.7 cm (DIN size A4)	Solid black areas pole. Fig.(s)
21.6 cm by 27.9 cm (8 1/2 x 11 inches)	Solid black shading not permitted. Fig.(s)
All drawings sheets not the same size.	Shade lines, pale, rough and blurred. Fig.(s)
	12. NUMBERS, LETTERS, & REFERENCE CHARACTERS.
MARGINS. 37 CFR 18.4(g): Acceptable margins:	37 CFR 1.48(p)
Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size	Numbers and reference characters not plain and legible.
Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm	. Fig.(s)
SIZE: 8 1/2 x 11	Figure legends are poor. Fig.(s)
Margins not acceptable. Fig(s)	Numbers and reference characters not oriented in the same
Top (T) Left (L)	
Right (R) Bottom (B)	English alphabet not used. 37 CFR 1.84(p)(3) Fig.(s)
VIEWS. CFR 1.84(h)	Numbers, letters and reference characters must be at least
REMINDER: Specification may require revision to	.32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig.(s)
correspond to drawing changes.	13. LEAD LINES. 37 CFR.1.84(q)
Views connected by projection lines or lead lines.	Lead lines cross each other. Fig.(s)
Fig.(s)	Lead lines missing. Fig.(s)
Partial views, 37 CFR 1.84(h)(2)	14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.48(i)
Brackets needed to show figure as one entity.	Sheets not numbered consecutively, and in Ababic numerals
Fig.(s)	beginning with number 1. Fig.(s)
Views not labeled separately or properly.	15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
Fig.(s)	Views not numbered consecutively, and in Abrabic numerals,
Enlarged view not labeled separately or properly.	beginning with number 1. Fig.(s)
Fig.(s)	16. CORRECTIONS. 37 CFR 1.84(w)
	Corrections not made from PTO-948 dated
•	17. DESIGN DRAWINGS, 37 CFR 1.152
	Surface shading shown not appropriate. Fig.(s)
	Solid black shading not used for color contrast.
	Fig.(s)
	11843)

Atty. Docket J25-277

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to:
BOX NON-TEE AMEMMENT Assistant Commissioner for Patents Washington, D.C. 2021 on October 4, 1999

October 4,1999



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Ferguson, et al.

Serial No.

09/050,536

Filing Date

March 30, 1998

For

LOTIONS AND GELS WITH ACTIVE INGREDIENTS IN BEADS

Examiner

Spear, J.

Group Art Unit

1615

BOX NON-FEE AMENDMENT Assistant Commissioner for Patents Washington, D.C. 20231

AMENDMENT

Sir:

In response to the Office Action dated July 2, 1999, please amend the above-identified application as follows:

line 5, before "friable" insert --visible--

Claim 15, line 1, change "claims 13 and 14" to --claim 13-

REMARKS:

Claims 1-20 are in the case and presented for consideration. Claim 15 has been corrected to depend only from claim 13, and the independent claims have been amended to explain that the beads are, in fact, visible. Please find support for this amendment at page 12, lines 6-8, for example.

The Examiner has rejected claims 1-19 as being fully anticipated by Noda, et al. Applicants gratefully acknowledge the Examiner's indication of allowability for claim 20.

It is sincerely believed, however, that the claims now presented are clearly patentable over the prior art in that the person having ordinary skill in this field would certainly not find the claimed invention obvious.

U.S. Patent 5,089,269 to Noda, et al. teaches that the weight ratio of a hydrophobic component, i.e. the material contained in the capsule to the gelatin that makes up the capsule, is between 1:10 to 100:1. Thus, at the lower end, the capsule loading of ingredients is between one part ingredient and ten parts gelatin: 1/11 or 9.09% by weight ingredients to 10/11 or 90.9% by weight

gelatin wall. At the upper end, capsule loading is one hundred parts ingredient and one part gelatin: 100/101 or 99% by weight ingredients to 1/101 or 1% by weight gelatin wall.

Dire consequents are repeatedly taught in Noda, et al. if the weight ratio of the gelatin wall exceeds 1:10. If the weight percent of actives contained in the gelatin capsule is less than 9.09%, for example, the capsule walls become too thick, escape of the capsules become marked, the capsules can not be easily broken and further, even if broken, portions of the wall film remain to give a feeling of foreign matter to the skin. (See Noda, et al. at column 9, line 59 to column 10, line 3, column 11, line 67, to column 12, line 5; column 13, line 14 to 18; column 14, line 26 to 30; column 15, lines 55 to 59; column 17, lines 17 to 22; column 19, line 10 to 14 and comparative examples in tables on column 23, line 16; column 25, line 54; column 26, line 58; column 29, line 3; column 36, line 7; column 37, line 54; column 38, line 42; column 41, line 5; column 42, line 33; column 43, line 23; column 45, line 50; column 47, line 57; column 50, line 13).

The present application teaches a very low concentration of core material (0.5% to 5.0%) is an effective way to provide controlled release and visual indication of product coverage, which is contrary to general teaching in the field. specification at page 2, lines 11 to 13 and page 3, lines 10 to 12). The present application teaches an ingredient to capsule

weight ratio of 0.005:1 to 0.05:1; i.e. 0.5% to 5.0% by weight active ingredients, the remainder being wall material.

Both the present application and Noda, et al. measure the same capsule breakage attributes:

- a) Noda, et al. measures capsule break strength instrumentally (column 14, lines 31 to 53) and by human sensory evaluation (column 25, lines 42 to 49).
- b) The application utilizes mechanical (page 9, line 23; page 12, lines 1 to 10; page 17, line 24 to page 18, line 19) and sensory evaluation (Visual: page 8, lines 26 to 27; page 13, lines 23 to 30; page 14, lines 11 to 15; page 18, lines 5 to 12; page 20, lines 20 to 22 and skin feel: page 12, lines 8 to 10; page 12, lines 14 to 20; page 12, line 26 to page 13, line 2; page 14, lines 6 to 11; page 15, lines 9 to 15; page 18, lines 16 to 24) to measure break strength.

The person of ordinary skill in this field, thus, reading Noda, et al. would actually receive contrary teaching to the invention of claims 1, 12 and 19, in that the skilled artisan is taught that much more of the active ingredient must be supplied in each capsule, and each capsule must have a much thinner wall thickness or else it will not break.

Claims 1 and 19 distinguish the invention even further in that the beads are visible and have a color which is used as a color indicator. There is not indication that Noda, et al. contemplates or suggests any purpose for having visible beads, and certainly no color indication function by virtue of rupturing of the beads.

Although claim 12 does not require the beads to have a color, it does call for the beads to be visible.

Noda, et al. also teaches a specific formulation which produces immediate break strength with no induction period. See, for example, claims 4 and 18.

This has been found by the inventors to be particularly useful during the manufacturing process and during use of the present invention for its intended purpose, whether the capsules are broken only by massaging the carrier with capsules into the skin, or by virtue of pumping the carrier with beads through a pump (allowable claim 20).

See, for example, Noda, et al. at column 7, lines 26-37; column 21, lines 1-12, 17-19, 27-29, 37-39 and 48-52. immediacy of the final break strength in Noda, et al. is formulated into the bead at the time of preparation. See Noda, et al. at example 6-2 on column 47, line 14, to column 48, line 11.

The Examiner is also requested to review Figs. 1 and 2 of the present application which give a visual indication of exactly how thick the capsule wall, and how small the active ingredient volume is according to the present invention. The skilled artisan considering Noda, et al. would have no reason to provide capsules with this geometry, certainly without first reading the present application.

The dependent claims distinguish the invention even further from Noda. For example, the combination of diameters and wall thicknesses (claims 5, 11 and 16, for example) would have to be deduced by a skilled artisan without help from the teaching of Noda, et al. Although the Examiner states that the skilled artisan would immediately envision minor modifications relating to carriers and containers for dispersing the carrier with beads, the skilled artisan would not contemplate providing beads with so little capacity for active ingredients and would certainly not teach the person of ordinary skill in this field any reason for providing beads of that type.

Other claims, such as claims 7-9, provide combinations of fragrance oils, particularly an oil which is skin activated in the beads and oil, which is a bulk fragrance in the carrier. In this way, the massaging of the beads after the carrier has been discharged on to the skin, discharges and thus activates the skinactivated fragrance exactly where it does the most good (on the skin) while retaining a pleasant fragrance for the carrier by virtue of the bulk fragrance.

When the capsules or beads are used as an indicator, then there is a rationale for providing the relatively massive walls containing colorant, since the walls themselves act as the indicator. Since Noda does not contemplate such massive walls, and

while providing colorant in some of the wall formulations does not contemplate use of the color as an indicator, the skilled artisan would have no reason to practice a method such as that called for in claims 13 or 19, for example.

For the foregoing reasons, the Examiner is respectfully requested to review this application and find the claims and application to be in condition for allowance.

Further favorable action is respectfully requested.

Dated: October 4, 1999

Respectfully submitted,

Peter C. Michalos Reg. No. 28,643

Attorney for Applicants

(212) 564-0200

PCM: cm

NOTARO & MICHALOS P.C. Empire State Building 350 Fifth Avenue Suite 6902 New York, New York 10118-6985

	Application No. 09/050,636	Applica(s)	FERGUSON,	ET AL.
Notice of Allowability	Examiner JAMES M. SF	EAR	Group Art Unit 1615	
All claims being allowable, PROSECUTION ON THE MERIT herewith (or previously mailed), a Notice of Allowance and mailed in due course.	S IS (OR REMAINS) (d issue Fee Due or at	CLOSED in t her appropri	his application. ate communica	If not included
★ This communication is responsive to THE AMENDMEN	T FILED OCTOBER O	7, 1999		·
The allowed claim(s) is/are 1-20				·
☐ The drawings filed on are accep	table.			
☐ Acknowledgement is made of a claim for foreign priorit ☐ All ☐ Some* ☐ None of the CERTIFIED copies ☐ received.	ty under 35 U.S.C. §		Jeen .	
received. received in Application No. (Series Code/Serial N	(umber)	:		·
received in this national stage application from the		u (PCT Rule	17.2(a)).	
*Certified copies not received:				
Acknowledgement is made of a claim for domestic prior	rity under 35.U.S.C.	§ 119(e).	· · · · · · · · · · · · · · · · · · ·	
A SHORTENED STATUTORY PERIOD FOR RESPONSE to THREE MONTHS FROM THE "DATE MAILED" of this Offic ABANDONMENT of this application. Extensions of time me	comply with the requi	rements not	ly will result in	ı
Note the attached EXAMINER'S AMENDMENT or NOTI that the eath or declaration is deficient. A SUBSTITUT	ICE OF INFORMAL AI E OATH OR DECLAR	PPLICATION ATION IS R	I, PTO-152, WI EQUIRED.	nich discloses
Applicant MUST submit NEW FORMAL DRAWINGS				
Decause the originally filed drawings were declared	by applicant to be inf	ormal.		
	erson's Patent Drawin	ng Review, I	PTO-948, attac	hed hereto or
 including changes required by the proposed drawing approved by the examiner. 	correction filed on		, whi	ch has been
☐ including changes required by the attached Examine	r's Amendment/Com	ment.		
Identifying indicia such as the application number (see drawings. The drawings should be filed as a separate p Draftsperson.	37 CFR 1.84(c)) shou paper with a transmit	ld be writte tel lettter ac	n on the revers kiressed to the	se side of the Official
□ Note the attached Examiner's comment regarding REQ	UIREMENT FOR THE	DEPOSIT OI	F BIOLOGICAL	MATERIAL.
Any response to this letter should include, in the upper rig CODE/SERIAL NUMBER). If applicant has received a Notic and DATE of the NOTICE OF ALLOWANCE should also be	e of Allowance and Is	PPLICATION Sue Fee Du	N NUMBER (SE e, the ISSUE B	RIES ATCH NUMBER
Attachment(s)				
☐ Notice of References Cited, PTO-892				
Information Disclosure Statement(s), PTO-1449, Page 1	per No(s)			
Notice of Draftsperson's Patent Drawing Review, PT	ro-948	\circ	10370	locas)
☐ Notice of Informal Patent Application, PTO-152		y	amou in	Spear EXAMENER
☐ Interview Summary, PTO-413		P	RIMARY	EXAMENER
Examiner's Amendment/Comment				
Examiner's Comment Regarding Requirement for De	posit of Biological Ma	rteriai //	CIUNI	-1 /613
Examiner's Statement of Reasons for Allowance				
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Application/Control Number: 09/050,536

Art Unit: 1615

Page 2

The following is an examiner's statement of reasons for allowance:

Applicants show a distinct structured bead comprised of an active ingredient dispersed in a carrier liquid and a method of using such a composition. The prior art shows microcapsules, particles and beads utilized in liquid compositions are known. Noda et al U.S. 5,089,269 considered the closest prior art of record shows a cosmetic composition comprised of microcapsules enclosing a hydrophobic component. The prior art does not show nor fairly suggest applicants' bead composition wherein the beads have a wall thickness of between about 210 and 740 microns, which may further have a colorant incorporated in the wall. The thick wall allows the microcapsule to be visible whether or not a colorant is present. The thick walled beads further have a lower amount of active ingredient capacity of approximately .5 to 5% by weight of the bead. Noda et al shows ratios of the hydrophobic component to be enclosed to components forming the gelatin capsule of 1:10 to 100:1, which would be no less than 9% active ingredient. The combination of low active ingredient concentration and distinct wall properties provides a means for effective controlled release of active agent and visual identification of bead components not shown nor recognized in the prior art.

Application/Control Number: 09/050,536

Page 3

Art Unit: 1615

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 1-20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Spear whose telephone number is (703) 308-2457. The examiner can normally be reached on Monday thru Friday from 6:30 A.M. to 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-3592 or 308-4556.

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Application/Control Number: 09/050,536

Page 4

Art Unit: 1615

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

James M. Spear

December 16, 1999



UNITED STAT. SEPARTMENT OF COMMERCE Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM22/1/221

NOTARO & MICHALOS EMPIRE STATE BUILDING 350 FIFTH AVENUE SUITE 6902 NEW YORK NY 10118-6985

APPLICA*	TION NO. FIUI	TOT STAC DN	AL CLAMS	EXAMPLER	AND GROUP ART UNIT		DAT	E MAILED
	09/050,536	03/30/98	020	SPEAR, J	. • •	1 6	515	12/21/
First Named Applicant	FERGUSON,		. 35	USC 154(b)	term ext. =	0	Days	:.

LOTIONS AND SELS WITH ACTIVE INGREDIENTS IN BEADS

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١.	. A1	TYS DOC	KET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN, 1	YPE	SMALL EI	YTITY	FEE DUE		DATE DUE	·
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THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verily your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

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- III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT: REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Dated: January 24, 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Ferguson, et al. APPLICANT

09/050,536 SERIAL NO.

March 30, 1998 FILING DATE

LOTIONS AND GELS FOR

WITH ACTIVE

INGREDIENTS IN BEADS

EXAMINER Spear, J.

GROUP ART UNIT 1615

G10 BATCH NO.

Box ISSUE FEE Assistant Commissioner for Patents Washington, D.C. 20231

LETTER TO OFFICIAL DRAFTSMAN

Sir:

In response to the issuance of a Form PTO-948, "NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW", applicant submits herewith three (3) sheets; namely Figs. 1-4, labeled and in duplicate (a total of 6 sheets).

It is respectfully requested that the Official Draftsman $\,$ review and accept the corrected drawings.

A Notice of Allowance has been issued on December 21, 1999, and the issue fee is being paid concurrently with this submission.

Dated: January 24, 2000

Respectfully submitted,

PCM: cm Enclosure

Peter C. Michalos. Reg. No. 28,643 Attorney for Applicant

(212) 564-0200

NOTARO & MICHALOS P.C. Empire State Building 350 Fifth Avenue, Suite 6902 New York, New York 10118-0110

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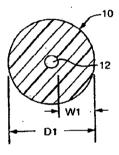


FIG. 1 ·

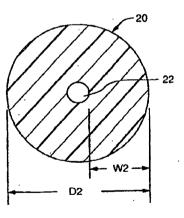


FIG. 2

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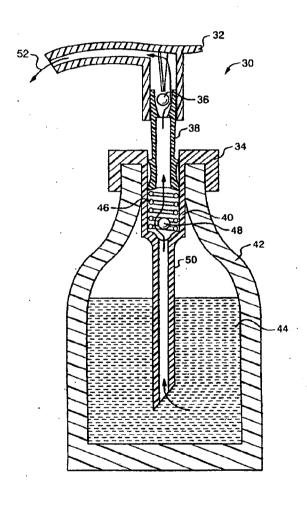


FIG. 3

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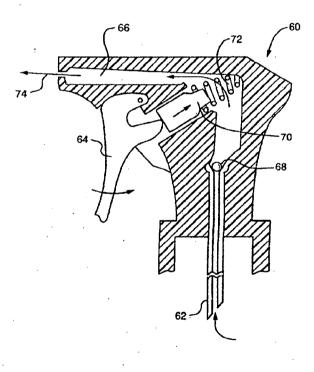


FIG. 4

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Cary McIver January 24, 2000 DATE MAILED EXAMINER AND GROUP ART UNIT

Patent and Trademerk Office; U.S. DEPARTMENT OF COMMERCE

APPLICATION NO. FILING DATE TOTAL CLAIMS 12/21/99 09/050,536 03/30/98 020 SPEAR, J 1615 First Named 35 USC 154(b) term ext. = 0 Days. FERGUSON,

CLASS-SUBCLASS BATCHNO. APPLN. TYPE SMALL ENTITY FEE DUE

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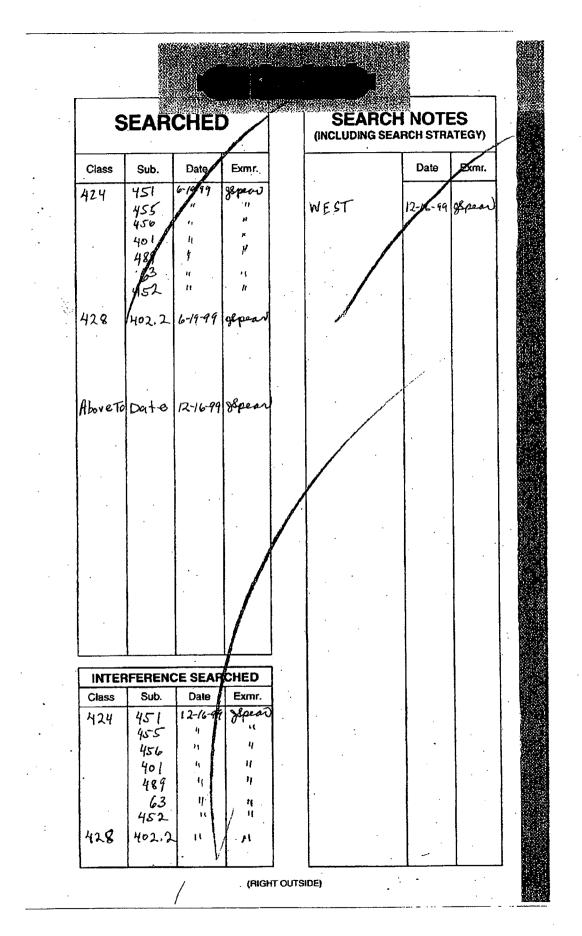


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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served on this 25th day of June, 2008 with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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E. Anthony Figg
Sharon L. Davis
C. Nicole Gifford
Daniel L. Shores
Rothwell, Figg, Ernst & Manbeck, P.C.
1425 K Street, N.W.
Suite 800
Washington, D.C. 20005

By:/s/ Francis G.X. Pileggi
Francis G.X. Pileggi (Del. Bar No. 2624)